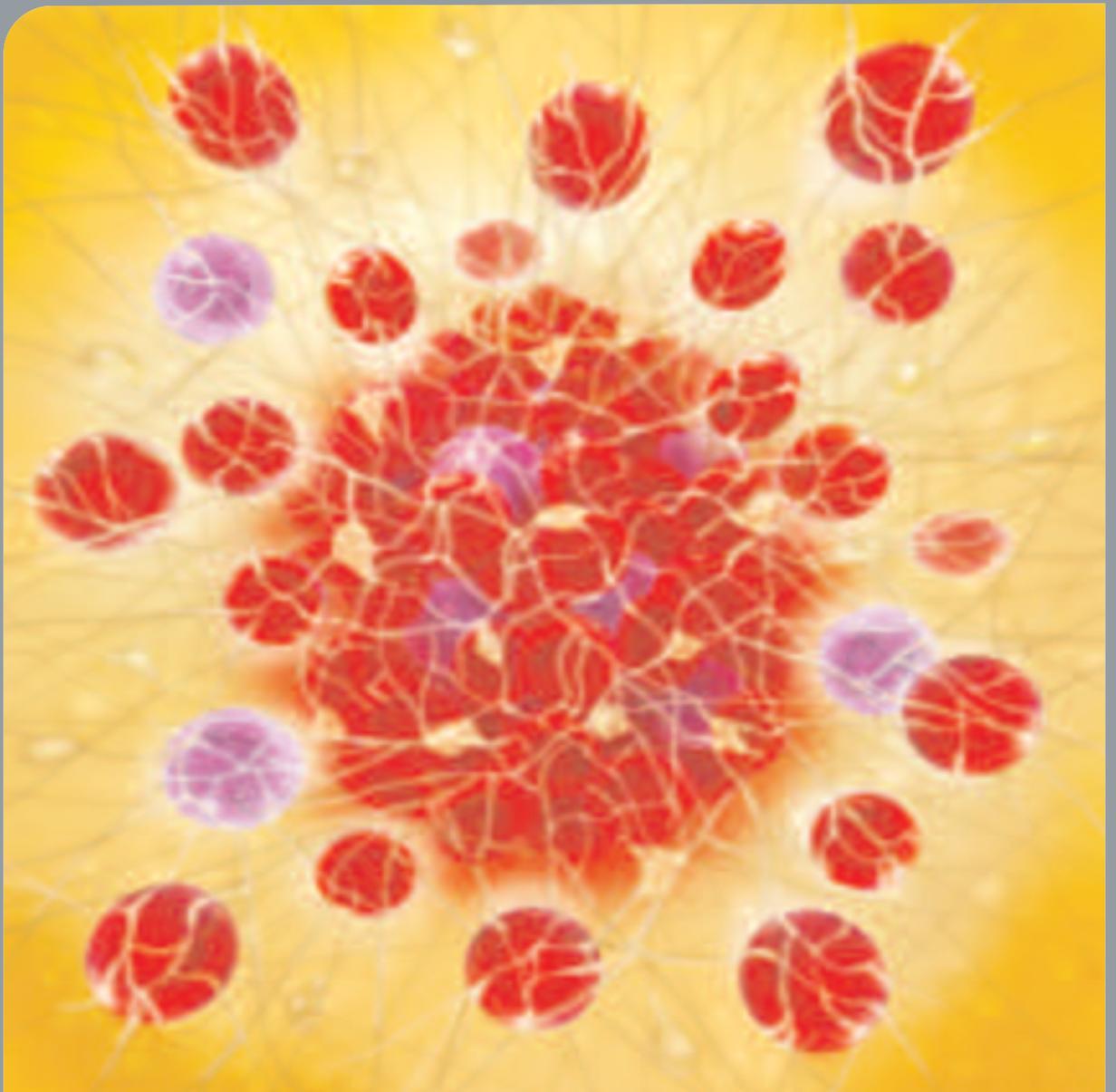


Risk assessment of anticoagulant therapy
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Professor David Cousins and Wendy Harris
Safe Medication Practice Team

Background

This risk assessment was undertaken to inform the work of the National Patient Safety Agency (NPSA); to better understand the risks associated with the use of anticoagulant medicines; and to identify possible safer practice solutions to be further developed, clarified and piloted by the NPSA and partner organisations.

This report is being published to share with interested parties information and the process that we used.

The information in this report provides the detailed background and evidence for the safer practice recommendations that the NPSA plans to make to the NHS and stakeholders in the first half of 2006.

Executive summary

In primary care, anticoagulants are one of the classes of medicines most commonly associated with fatal medication errors. In 2002 a coroner and the Chief Medical Officer (England) highlighted the death of a patient from a warfarin overdose caused by misinterpretation of a doctor's handwriting.

In secondary care, warfarin is one of the ten drugs most frequently associated with dispensing errors.

The NHS Litigation Authority has reported that medication errors involving anticoagulants fall within the top ten causes of claims against NHS trusts.

Anticoagulants were included in the Department of Health Report *Making Medication Practice Safer* (2004) as high risk medicines that require the implementation of additional safety controls.

The NPSA contacted the medical and pharmacy defence organisations as well as the NHS Litigation Authority for available data describing patient harm.

The NPSA was informed of 480 reported cases of patient harm from the use of anticoagulants in the UK up to the end of 2002. In addition, there have been 120 deaths reported. Of these deaths 77% (92 reports) were related to warfarin use and 23% (28 reports) associated with the use of heparin.

The NPSA communicated with patient groups, patients and carers to obtain their views concerning their use of anticoagulants.

A comprehensive literature review has been completed and a risk assessment exercise undertaken with a multidisciplinary group on the use of anticoagulants in the NHS.

Using all these methods, high risks were identified that contributed to the high incidence of patient harm with anticoagulants.

High risks identified

- 1 Not all staff who prescribe and monitor anticoagulants have received the necessary training and have the required work competencies.
- 2 Inadequate clinical audit of anticoagulant services and/or failure to act on audit results to improve the service.
- 3 Failure to initiate anticoagulant therapy (including thromboprophylaxis) where indicated.
- 4 Poor documentation of reason and treatment plan at commencement of therapy.
- 5 Prescribed wrong dose or no dose of anticoagulant (especially loading doses).
- 6 Unconsidered co-prescribing and monitoring of non-steroidal anti-inflammatories and other interacting medicines.
- 7 Incorrect selection, preparation and administration of heparin products.
- 8 Unsafe arrangements and communications at discharge from hospital.
- 9 Insufficient support and monitoring of warfarin therapy for the first three months and for vulnerable groups.
- 10 Inadequate safety checks at repeat prescribing and repeat dispensing in the community.
- 11 Confusion over anticoagulant management for dentistry, surgery and other procedures.
- 12 Non-standardised supply/use of 0.5mg, 1mg, 3mg and 5mg tablets.
- 13 Yellow book (patient-held information) in need of revision and translation into other languages.
- 14 Inflexible medicines presentations and arrangements in care homes to implement anticoagulant dose changes.
- 15 Inadequate Quality Assessment (QA) for near-patient testing equipment.

Important observations

Failure to implement professional guidelines concerning the prescribing, counselling, monitoring and administering of anticoagulants is an important underlying cause identified by the risk assessment process. This underlying cause has been perpetuated by local failure to effectively audit anticoagulant services, to act on audit results to improve clinical and process outcomes, and to alert clinical governance structures in NHS organisations of the extent of these risks.

The development of safer practice solutions and recommendations

The NPSA has identified possible safer practice solutions for anticoagulant use.

Possible safer practice solutions to be further developed, clarified and piloted

- 1 Ensure all staff who prescribe and monitor anticoagulants have received adequate training and have the necessary work competencies.
- 2 Regular monitoring of safety indicators for inpatient and ambulatory anticoagulant services, and results sent to trust clinical governance committees.
- 3 Improve guidelines for:
 - loading doses;
 - patients going for dental surgery, surgery, cardioversion and endoscopy;
 - QA for near-patient testing devices.
- 4 Promote the use of computer dosing software for decision support and audit.
- 5 Use of pharmacists and nurses to provide anticoagulant service, especially for hospital inpatients, and improved links between inpatient and ambulatory services.
- 6 Improve arrangements and communication when patients are discharged from hospital.
- 7 Improve safety checks when interacting medicines are being prescribed.
- 8 Improve support and monitoring of patients in the first three months of warfarin therapy and for vulnerable groups.
- 9 Clarify safety checks for GPs prescribing repeat prescriptions of anticoagulant products and of pharmacists' supplying anticoagulant products.
- 10 Revise design and content of patient-held record.
- 11 Standardise the way doses are prescribed and supplied.
- 12 Standardise the presentation and method of use for unfractionated heparin products.
- 13 Review methods for how anticoagulants are supplied and administered in care homes.
- 14 Improve the design of forms and software for prescribing, monitoring and administering anticoagulants.

Next steps

The NPSA plans to further clarify, develop and pilot safer practice solutions with stakeholders during 2005 to enable us to prepare draft recommendations for a wide stakeholder consultation in the first quarter of 2006.

The NPSA intends to publish final recommendations in the second quarter of 2006.

We will formally evaluate the implementation and outcome of the safer practice recommendations in 2007.

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1 Introduction

In primary care, anticoagulants are one of the classes of medicines most commonly associated with fatal medication errors (Medical Defence Union, 1996).

Case studies have been published to describe deaths associated with anticoagulant therapy (Machin, 2002; Reardon, Burns and Brewer, 1995; Ferner and Whittington, 1994).

A coroner and the Chief Medical Officer (England) have highlighted the death of a patient from a warfarin overdose caused by misinterpretation of a doctor's handwriting (Eaton, 2002; Anon, 2002; Department of Health, 2003).

In secondary care, warfarin and heparin errors are among the most frequently reported medication errors (Cousins and Upton, 1997; 1998).

Oral anticoagulants were included in the Department of Health report, *Making Medication Practice Safer* (2004) as high risk medicines that require the implementation of additional safety controls (Department of Health, 2004).

In the USA (Anon, 2001; JCAHO, 2000) and Australia (Runiciman, Roughead et al., 2003), anticoagulants have been identified in the top five medicine classes associated with patient safety incidents.

2 Objectives

The objectives of the risk assessment were to:

- describe and map the use of anticoagulant therapy in the NHS;
- identify and assess the risks at each step of the anticoagulant treatment process;
- identify and prioritise safety solutions to the anticoagulant processes and to re-evaluate the risks, acknowledging that safety solutions may introduce new risks, and increase existing risks as well as eliminating and reducing other risks;
- identify safety solutions to be developed as NPSA recommendations to the NHS to make anticoagulant treatment safer.

3 Description of anticoagulant therapy

This section provides a brief description of anticoagulant therapy to enable a non-technical reader to understand the background to the various processes to be reviewed.

There are several therapeutic guidelines that have been published that provide practical guidelines for healthcare practitioners on the range of indications where anticoagulants should be used and how patients should be dosed, managed, monitored and audited.

Guideline title	Author/professional organisation	Year	Country
Anticoagulant guidelines from the seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy	American College of Chest Physicians (ACCP)	2004	USA
Anticoagulant and aspirin prophylaxis for preventing thromboembolism after major gynaecological surgery	Cochrane Review	2004	UK
Thromboprophylaxis during pregnancy, labour and vaginal delivery.	Royal College of Obstetrics and Gynaecology	2004	UK
Prophylaxis of Venous Thromboembolism SIGN Publication No. 62	Scottish Intercollegiate Guidelines Network	2002	Scotland
Guidelines on oral anticoagulation: third edition	British Committee for Standards In Haematology, British Society of Haematology (BCSH)	1998	UK

There are two main types of anticoagulants: a) oral anticoagulants; and b) anticoagulants that have to be injected or infused.

3.1 Oral anticoagulants

It is estimated that in the UK there are approximately 500,000 patients prescribed oral anticoagulation to thin the blood and thereby provide prophylaxis against thrombotic events (blood clotting that can cause disease). The commonest clinical indications for the use of oral anticoagulants are: atrial fibrillation (abnormal beating of the heart that can cause blood pooling and embolus (clot) formation in the small chambers of the heart (atria); the treatment and prevention of deep vein thrombosis and pulmonary embolus (clot formation in the blood vessels in the lungs); and the treatment of patients with mechanical heart valves, where the artificial valves may lead to clot formation.

Warfarin is the most frequently prescribed oral anticoagulant medicine. Other, less commonly prescribed oral anticoagulants include phenindione and acenocoumarol (formerly nicoumalone). To use these medicines safely their dose needs to be adjusted to maintain the desired therapeutic action and minimise adverse side effects. Under-anticoagulation can result in thrombosis which can be life threatening. Equally over-anticoagulation can result in haemorrhage (bleeding) which can be fatal and outweigh the benefits of preventing the thrombosis (Fitzmaurice and Murray, 2002). Duration of treatment varies, from three to six months for venous thrombosis, to life for cardiac or recurrent thrombosis indications.

Patients must have regular tests (usually monthly) of the effect of the warfarin on their blood clotting, measured as an International Normalised Ratio (INR) and which may require adjustment of their tablet dose to ensure good, safe control. Some people are particularly sensitive to oral anticoagulants and in these individuals small increases in dosage, or introduction/discontinuation of interacting medicines, herbal preparations and certain foods including alcohol, can cause catastrophic increases in anticoagulant effect (Fitzmaurice, Hobbs and Murray, 1996).

Patients frequently have complex medical histories and may be taking other medications. Oral anticoagulants interact with a wide variety of other medicines (for example, antibiotics and analgesics which are commonly prescribed in primary care), in most cases leading to an increased anticoagulant effect. Patients taking anticoagulants should be aware of the risks of taking other prescribed or purchased medicines, herbal products and certain foods including alcohol without first seeking advice.

The dose of warfarin must be carefully adjusted for each patient. Patients are often given supplies of one or more strengths of warfarin tablets, i.e. 1 mg, 3 mg and 5 mg, to enable doses to be adjusted. Recently, 0.5 mg tablets have been introduced to enable more accurate dose adjustment.

Supplies of warfarin tablets in more than one strength may increase the risk of accidental overdose, especially in confused, older people (Reardon, Burns, Brewer, O'Sullivan, 1995). Low literacy and numeracy skills have been associated with measures of poor anticoagulation control (Estrada et al., 2004).

Many patients are frail and elderly, making frequent attendances for blood tests difficult. Successful, safe anticoagulation depends on patient education, good compliance and good communication with both patient and those various individuals responsible for their clinical and social care.

The scope for occurrence of an adverse event related to warfarin is large because of the biological variation in response to treatment and because of the large number of individuals involved in the patient's care. Most published literature relates to pathological consequences, such as major or minor haemorrhage or thrombosis, and does not directly correlate the incident with the quality of care delivered. It is accepted as a good standard of care if patients are within the target range of INR 60% of the time (Machin, 2002). Risk of haemorrhage whilst on long term anticoagulation varies between 1 and 15% per annum (Fitzmaurice 2002). Risk of death increases the greater the INR (Oden, 2002) but death may be due to co-morbidity; a high INR being an indicator of end stage disease (Chan and Woodruff, 1992).

A meta-analysis of studies using oral anticoagulant treatment for venous thromboembolism (VTE) has shown that major bleeding can have a serious clinical impact in these patients. For all patients, the rate of major bleeding was just over 2% in the first three months, falling significantly thereafter. The risk of major bleeding was greatest at the start of treatment – the rate was nearly as high for the first three months as for the entire year after this period (Linkins, Choe, Douketis, 2003).

3.2 Anticoagulants that have to be injected or infused

Heparin is an anticoagulant that has to be injected as it is not active when taken orally. It is used in high doses to treat venous thromboembolism (deep vein thrombosis and pulmonary embolism) and in lower doses for prophylaxis (prevention) of thromboembolism in surgical patients and pregnant women at risk. It is also used in the management of arterial thromboembolism including that associated with unstable angina, myocardial infarction and stroke.

Heparin acts very quickly (in minutes), whereas warfarin acts more slowly (in days). Patients with thromboembolism are usually treated initially with heparin and warfarin, and heparin is withdrawn after five days once the warfarin is exerting its full effect.

Sodium heparin

This product is administered in therapeutic doses by continuous intravenous infusion using a syringe driver pump. It is also administered by subcutaneous injection in lower doses, two or three times a day for its prophylactic action.

Calcium heparin

This product is administered in therapeutic doses by subcutaneous injection two or three times a day. In lower doses it is administered by the same route for prophylaxis.

Control of sodium and calcium heparin therapy

All therapeutic doses have to be monitored on a regular, usually daily, basis to ensure the dose is providing the required anticoagulant effect. The most common blood tests for patients on heparin are the Kaolin Cephalin Clotting Time (KCCT) or Activated Partial Thromboplastin (APPT) tests. Frequent dose adjustments are usually required over five to seven days therapy to ensure effective anticoagulation and prevent complications of bleeding.

Low molecular weight heparins

These are newer products introduced to practice in the 1990s. There are a number of medicines in this therapeutic class, e.g. dalteparin, enoxaparin, tinzaparin. Low molecular weight heparins (LMWH) doses are determined according to the weight of the patient.

Doses need to be altered for obese patients and lean body weight should be used (Green and Duffull, 2003; Mathews and Davies, 2002; Frederiksen et al., 2003; Smith and Canton, 2003). Blood tests are not generally needed to ensure therapeutic blood levels and blood clotting. These medicines are given once or twice daily by subcutaneous injection both for treatment and for thromboprophylaxis. A number of studies have provided evidence that the use of low molecular weight heparin products, that do not require any laboratory monitoring, improves clinical effectiveness, safety and cost effectiveness (Aujesky, 2004; Buller, Gent et al., 1996; Simmonneau, Sors et al., 1997; Valette, Hoffmeyer and Lloyd, 1995). As with other anticoagulants, precautions need to be taken during the perioperative period (Mathews and Davis, 2002). UK hospitals now use this type of heparin therapy for the majority (but not all) of their patients requiring injectable anticoagulants.

Side effects of heparin products

Potential adverse effects of heparin include bleeding; this is especially possible in patients who have had recent surgery or trauma. It can also occur in patients who have disorders of their blood clotting system. These medicines can rarely cause allergic reactions. Osteoporosis can occur in patients who are administered heparin for long periods of time.

The use of anticoagulant therapy in children

Thromboembolic disease is increasingly recognised as a major cause of morbidity and mortality in tertiary paediatrics. Children younger than one year and teenage girls are at greatest risk of thromboembolism. Recommendations for anticoagulant therapy in children have been loosely extrapolated from recommendations for adults. However, it is likely that optimal treatment for children differs from adults because of important ontogenic features of haemostasis that affect both the pathophysiology of the thrombotic processes and the response to anticoagulants. (Ronghe et al., 2003). The American College of Chest Physicians (ACCP) has provided guidelines for the use of anticoagulants in children (Monagle et al., 2004). The ACCP notes that the majority of literature to support the current recommendations are uncontrolled studies, case reports or in vitro experiments and that well-designed studies are required to validate the current guidelines. Paediatric patients on warfarin therapy may also require their therapy to be formulated and presented in a liquid preparation. There are no commercial formulations of warfarin available in the UK and these medicines have to be prepared extemporaneously in the pharmacy. Despite these additional complications there is little published evidence of patient safety incidents involving anticoagulant therapy in children.

4 The extent of patient safety incidents and risks

To determine the extent of patient safety incidents and risks with anticoagulant therapy, we have considered published literature, negligence literature and NPSA incident report data.

4.1 Negligence claims reports

The NPSA contacted the medical and pharmacy defence organisations as well as the NHS Litigation Authority.

There have been 600 patient safety incidents of harm or near harm associated with the use of anticoagulants in the UK between 1990 and 2002. Of these cases, 20% (120) have resulted in the death of the patient.

Death associated with the use of warfarin is responsible for 77% (92 reports) and death associated with heparin is responsible 23% (28 reports).

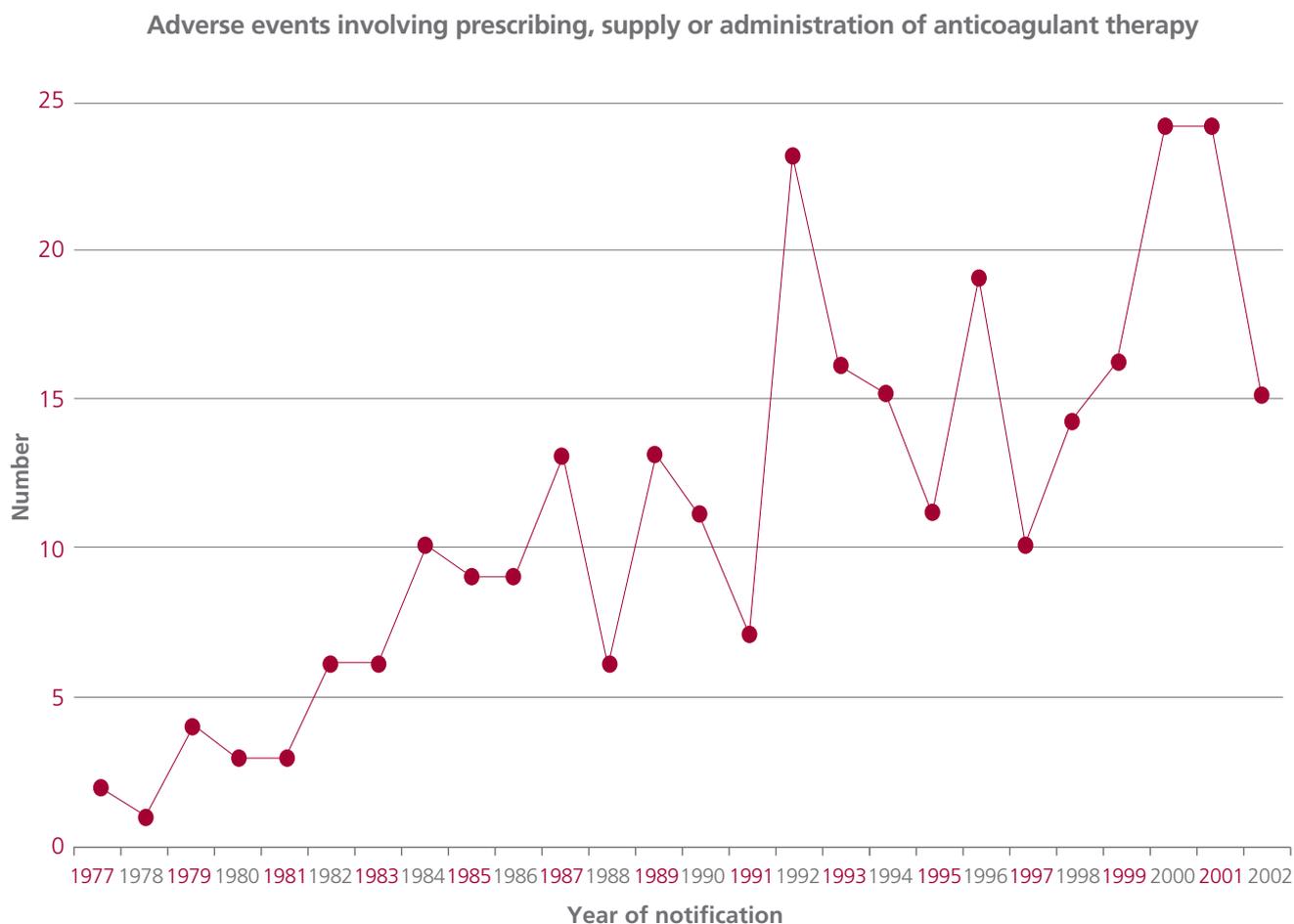
Further analysis of the data from the Medical Defence Union (MDU) was possible. Fatal incident reports from this source concerning warfarin made up 88% (79 reports) of the total 92 reports.

Deaths associated with the use of warfarin in primary care were 76% (60 reports) of the total reported to the MDU (79 reports). The main types of causes for these fatal incidents were: 1) inadequate laboratory monitoring; and 2) clinically significant drug interactions usually involving non-steroidal anti-inflammatories.

Fatal incident reports concerning heparin in secondary care from the MDU made up 93% (26 reports) of the total of 28 reports. The main causes of these fatal incidents were: 1) inadequate laboratory monitoring; 2) inappropriate cessation; 3) inappropriate use of heparin when contraindicated; and 4) dose miscalculation.

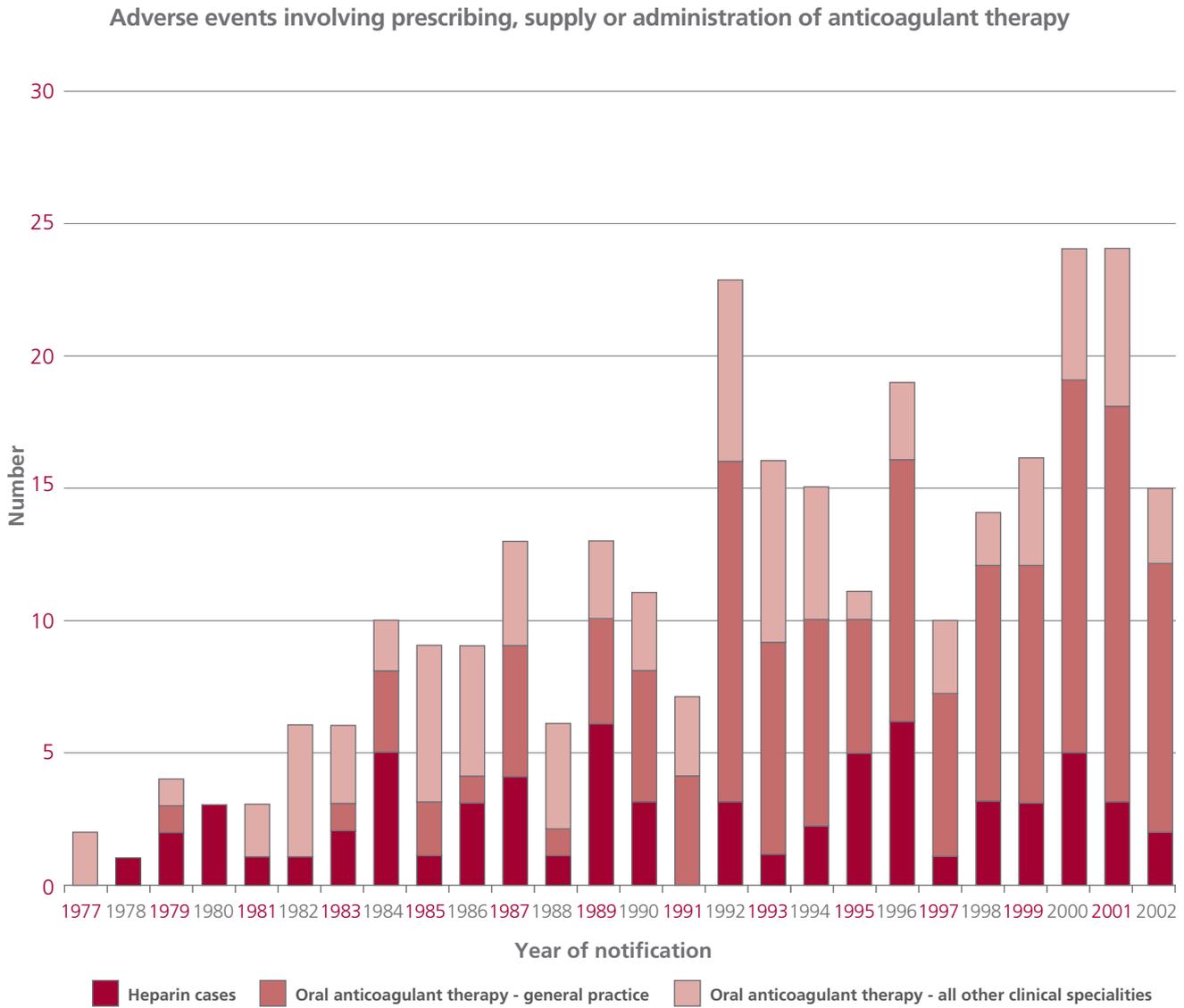
The Medical Defence Union has also informed the NPSA that the number of negligence claims involving anticoagulants has increased since 1990. See Figures 1 on page 11 and Figure 2 on page 12.

Figure 1: Trend analysis of reports involving anticoagulants received by the Medical Defence Union 1977-2002



Copyright: The MDU March 2003
Anticoagulants/hmg

Figure 2: Trend analysis of reports involving anticoagulants received by the Medical Defence Union 1977-2002 by drug and sector of care



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Anticoagulants/hmg

Details of MDU negligence claims reports

From general medical practice

Death	60
Inadequate monitoring/dosing	36
Known interaction with:	
Antibiotic	8
Non - Steroidal Anti Inflammatory (NSAI)	6
Antidepressant	1
Inappropriate cessation of warfarin therapy	5
Wrong drug prescribed: warfarin instead of torazosin	1
Overdose due to illegible prescription	1
Failure to visit patient with head injury on warfarin	1
Failure to visit patient with massive haemorrhage	1
Permanent harm	14
Inadequate monitoring/dosing	5
Inappropriate cessation of warfarin therapy	2
Known interaction with:	
Antibiotic	1
NSAI	2
Norethisterone	1
Bezafibrate	1
Delayed diagnosis	1
Contraindicated by pregnancy	1

Temporary harm or no harm	60
Inadequate monitoring/dosing	28
Delayed treatment	2
Inappropriate cessation of warfarin therapy	1
Failure to prescribe the requested dose	2
Known interaction with:	
Antibiotic	5
NSAI	11
Danazol	1
Cholestyramine	1
Generic and proprietary warfarin prescribed together	1
Wrong drug dispensed, warfarin instead of folic acid, thyroxine	2
Delayed reporting due to computer failure	1
Wrong dose dispensed	3
Failure to stop warfarin prior to surgery	1
Failure to diagnose	1

Not from general medical practice

Death	20
Inadequate monitoring/dosing	4
Known interaction with:	
Antibiotic	1
NSAI	4
Inappropriate cessation of therapy	2
Failure to warn of risks of warfarin when pregnant	4
Failure to stop warfarin before surgery as requested	1
Failure to prescribe	1
Delayed diagnosis	1
Premature discharge	1
Communication failure regarding dose	1
Permanent harm	40
Inadequate monitoring/dosing	27
Inappropriate cessation of warfarin therapy	5
Known interaction with:	
Antibiotic	1
NSAI	2
Delayed diagnosis	3
Failure to prescribe	1
Failure to restart after surgery	1

Temporary harm or no harm	29
Inadequate monitoring/dosing	7
Inadequate pre-operative assessment	2
Known interaction with:	
Antibiotic	1
Danazol	1
NSAI	5
Anticonvulsant	1
Peeling agent	1
Inappropriate prescribing	1
Wrong dose prescribed: warfarin dose on sinthrome	1
Refusal to perform extraction on a patient taking warfarin	1
Failure to check INR before dental/surgical procedure	7
Wrong diagnosis	1

Published reviews of drug and food interactions with oral anticoagulants have been undertaken (Holbrook et al., 2005; Rice et al., 2003; Williamson, 2005; Stockley, 2002). The incidence and possible causes of prescribing potentially hazardous/contraindicated drug combinations in general practice has also recently been reviewed (Chen et al., 2005).

4.2 NPSA patient safety incident data

There were 1,250 patient safety incident reports involving anticoagulants (all types) reported to the NPSA via the National Reporting and Learning System, mainly from acute NHS hospital trusts, between 1 September 2004 and 31 December 2005. Omitted and wrong doses were the most frequent types of incident reported.

Incidents involving warfarin (n = 699)

Error type	Number of reports (%)
Prescribing	201 (29%)
Preparation and dispensing	46 (7%)
Administration	379 (54%)
Monitoring	45 (6%)
Other	28 (4%)

Outcome	Number of reports (%)
Death	1 (<1%)
Severe harm	5 (<1%)
Moderate harm	34 (5%)
Low harm	110 (16%)
No harm	549 (79%)

Type of incident	Number of reports (%)
Omitted medicine	252 (36%)
Wrong dose/frequency/quantity	219 (31%)
Mismatching patients with treatment	38 (5%)
Wrong drug	39 (6%)
Contraindication	32 (5%)
Other	119 (17%)

Incidents involving heparin (n = 416)

Error type	Number of reports (%)
Prescribing	56 (14%)
Preparation and dispensing	18 (4%)
Administration	318 (76%)
Monitoring	20 (5%)
Other	4 (1%)

Outcome	Number of reports (%)
Death	1 (<1%)
Severe harm	1 (<1%)
Moderate harm	20 (5%)
Low harm	68 (16%)
No harm	325 (78%)

Type of incident	Number of reports (%)
Omitted medicine	44 (12%)
Wrong dose/frequency/quantity	200 (56%)
Mismatching patients with treatment	8 (2%)
Wrong drug	26 (7%)
Contraindication	9 (3%)
Other	70 (20%)

Incidents involving unspecified anticoagulants (n = 135)

Error type	Number of reports (%)
Prescribing	39 (29%)
Preparation and dispensing	10 (7%)
Administration	65 (48%)
Monitoring	16 (12%)
Other	5 (4%)

Outcome	Number of reports (%)
Death	0 (0%)
Severe harm	2 (1%)
Moderate harm	7 (5%)
Low harm	17 (13%)
No harm	109 (81%)

Type of incident	Number of reports (%)
Omitted medicine	35 (26%)
Wrong dose/frequency/quantity	52 (39%)
Mismatching patients with treatment	6 (4%)
Wrong drug	4 (3%)
Contraindication	5 (4%)
Other	33 (24%)

4.3 Published audits and reports

Report summary	Primary author	Year	Country
Records from 36,157 clinic visits of 2,050 patients were studied. 52.3% were within the therapeutic range. The quality of anticoagulant control changed little with the length of time between clinic appointments.	Utley	2005	UK
To evaluate patients' non valvar atrial fibrillation maintained on warfarin with an INR target of 2.0-3.0. Some 2,223 patients reviewed. Patients outside the target range 32.1% of time. 15.4% >INR 3.0, 16.7% >INR 2.0. Quartile with worst control spent 71.6% of their time outside range, compared with 16.3% of patients in the best controlled quartile. A multivariate analysis showed a 10% increase in time out of range was associated with an increased risk of mortality (odds ratio 1.29) or ischaemia stroke (odds ratio 1.10) or other thromboembolic events (odds ratio 1.12). The rate of hospitalisation was higher when the INR was outside target range. New measures are needed to improve maintenance anticoagulation.	Jones	2005	UK
Review of anticoagulant errors in a hospital setting over a three year period. 130 errors were identified. There were 1.67 errors for every 1,000 patients treated. Most often associated with unfractionated heparin (66.2%), followed by warfarin (21.5%), low molecular weight heparin (9.2%), argatroban (1.5%) and lepirudin (1.5%). There were no deaths, but 6.2% of patients required medical intervention and 1.5% needed prolonged hospitalisation.	Fanikos	2004	USA
18,820 adult patients admitted over six months assessed for cause of admissions. There were 1,225 admissions related to ADR's giving a prevalence of 6.5% with the Adverse Drug Reaction (ADR) directly leading to the admission of 80% of cases. Most reactions were avoidable. Warfarin alongside non-steroidal anti-inflammatory agents was most commonly associated with the clinically significant ADR. The most common reaction being gastro-intestinal bleeding.	Pirmohammed	2004	UK
Retrospective, age stratified, event driven clinical database analysis. 739 patients receiving warfarin for Non Rheumatic Atrial Fibrillation (NRAF) between 1996 and 2001. Over 1,484 patient years, computer assisted anticoagulation was uncontrolled in 38.3% of patients (INR < 2.0 or > 3.0). No significant differences in INR control were observed with respect to patient age (< 65, 65-75, and > 75 years), although to achieve adequate control of anticoagulation, the frequency of testing increased significantly with age. Annual risks of bleeding complications, thromboembolism and stroke were 0.76%, 0.35%, and 0.84% respectively. No significant differences in these events were observed between the three age groups studied. Patients who had thromboembolic events and haemorrhagic complications were significantly more likely to have been under-anticoagulated (INR < 2.0) and over-anticoagulated (INR > 3.0) respectively, at the time of their clinical event. Computerised long term oral anticoagulation for NRAF in a community setting of elderly and diverse patients is safe and effective. Anticoagulation control, bleeding events, thromboembolic episodes, and stroke rates are directly comparable with those reported in major clinical trials.	Yousef	2004	UK

Report summary	Primary author	Year	Country
A meta-analysis of 33 trials involving 4,374 patient years of anticoagulant therapy. Case fatality rate of intracranial bleeding was 13.4%. The rate of intracranial bleeding was 1.15 per 100 patient years. For patients who received anticoagulant therapy for more than 3 months the case fatality rate of major bleeding was 9.1% and the rate of intracranial bleeding was 0.65 per 100 patient years.	Linkina	2003	Canada International review
A systematic review of outcome measures reported for the therapeutic effectiveness of oral anticoagulation was undertaken. Fifteen papers published in the previous five years were reviewed. Outcome measures used varied and included: reported time within therapeutic range; mean INR proportion in range; mean warfarin dose; dose changes each month; time between visits; and median INR values. Six papers only reported using one measure. Six papers used two measures and two papers reported three outcome measures. Authors concluded at least two measures should be used to monitor INR determination and dosing advice.	Fitzmaurice	2003	UK
1,480 acute admissions to hospital were reviewed over three months. 112 (7.6%) were on anticoagulant therapy. 103 of these patients were evaluated. 29 patients were over-anticoagulated and of these 17 (59%) were admitted with bleeding symptoms. Reasons for over anticoagulation were poor compliance (31%), influence of other medications (17%), congestive heart failure (28%), and unknown (24%). 22/1480 (1.5%) of hospital admissions were due to warfarin complications and 16/21 bleeding patients had INRs >4.5. These admissions could have been avoided with better anticoagulant control.	Hiri	2002	UK
Meta-analysis of controlled trials to examine the benefits and risks of long term warfarin therapy compared to antiplatelet treatment (aspirin/ibuprofen) in patients with non-rheumatic atrial fibrillation. There were five trials published between 1989 and 1999. There were no significant differences in mortality between the two treatment options for stroke deaths. There was borderline significant difference in combined fatal and non fatal events. There were more major bleeding events among patients on anticoagulants than on antiplatelet treatment. Review of trial data shows uncertainty about the value of long term anticoagulants compared with antiplatelet treatment and the risks of bleeding and the higher costs of anticoagulation make it an even less convincing treatment option.	Taylor	2001	UK
An audit of inpatient therapy with unfractionated heparin was conducted for two months. In the 161 days of therapy with unfractionated heparin the APTT was measured in 43% of occasions and was in the therapeutic range in 17% of occasions.	Tweed	2000	UK
Review of all patients on oral anticoagulants with an INR >8 in a 12 month period. From a total of 55,625 INRs, 131 were >8. A major cause of over-anticoagulation was unsatisfactory dose loading during in-hospital commencement of oral anticoagulants. The incidence of major bleeding was 12.9% of the total episodes of INR>8, with two haemorrhage related fatalities. Therapy of major haemorrhage with fresh frozen plasma and intravenous vitamin K proved effective but was not given in the majority of cases. The authors recommend that severely over-anticoagulated patients without obvious bleeding should receive small doses of vitamin K to reduce the risk of haemorrhage related morbidity and mortality, without compromising the patient's subsequent oral anticoagulant control.	Murphy	1998	UK

Report summary	Primary author	Year	Country
A cohort of patients with an INR >7 were identified prospectively and compared to a group with stable control. Odds ratio calculations were performed to identify risk factors. The highest risk factor was a target INR of 3.5. The second highest factor was antibiotic therapy in the four weeks preceding the high INR. The INR>7 had five major bleeds compared with none in patients with stable control.	Panneerselven	1998	UK
Combined prescription and monitoring charts were developed for heparin and warfarin which incorporated clinical guidelines. Introduced into a 700 bed hospital. The percentage of time spent under-anticoagulated with heparin fell from 33% to 19% and there was no change for warfarin at 26%. The percentage time over-anticoagulated for heparin did not change at 5%, whereas the time for warfarin reduced from 5% to 3%. The combined charts led to a significant improvement in anticoagulant control.	Phillips	1997	UK
An audit of the initiation of warfarin therapy in 100 consecutive hospital inpatients. Problems in optimal anticoagulant control prior to discharge were identified largely due to poor dose selection and failure to take into account age, recurrent illnesses and potentially interacting drugs. Discharge delays were caused by anticoagulant difficulties affecting 25 of the 100 patients, representing a total of 68 extra inpatient days.	Sowter	1997	UK
One hundred case notes for patients starting anticoagulants were audited based in local guidelines. Identification of patient risk factors for anticoagulation by history taking and laboratory tests was often inadequate. There was a tendency to under treat patients with 33% APTT and 58% of INRs were sub-therapeutic. Of the 62 patients discharged from hospital on warfarin, 28% were discharged with an INR outside the normal range. At discharge 26% did not have documented appointments with the anticoagulant clinic. The period from discharge to the first appointment ranged from 0-12 days. Of the 25 cases with an appointment exceeding four days after discharge, only 6 (24%) had arrangements for an interim INR check and dose review.	Tan	1993	UK
An audit of referral letters to an anticoagulant clinic was audited prospectively for all new patients (80) over a eight month period. Referral letters were not received for 10% (8/80) of patients. Of the referral letters, information included: 99% indication for anticoagulation, 81% planned duration of therapy, 46% or less included other important clinical information such as date of starting therapy, current dose, latest INR result, other medical problems and concurrent treatment.	Tan	1993(a)	

4.4 Audit of thromboprophylaxis

Summary	Specialty	Reference	Year	Country
Discharge summaries and medical notes reviewed, and warfarin prescribing identified, in a Medicine for the Elderly department for 12 months before and 7 months after guideline intervention. Warfarin prescribing for suitable patients increased from 31.4% to 54.5%.	Medicine for the elderly	Lowden	2004	Scotland
A retrospective chart review of 100 patients admitted to a hospital medicine service was conducted. 31% of patients with established VTE risk factors and no documented risk factors for bleeding were prescribed prophylaxis. An established regimen was prescribed in only 19% of those receiving prophylaxis.	Medical	Stark	2004	USA
Audit of thromboprophylaxis after caesarean section. Retrospective audit of 200 consecutive patients. The majority of women (84.5%) had at least one risk factor for thromboembolism. Only 54% of cases received treatment.	Obstetrics	Gidiri	2004	England
All the 13 regional and national spinal injury referral centres within the British Isles were contacted to find out their protocols for thromboembolic prophylaxis in patients with acute spinal injuries. All units replied. A wide variation in methods used was found in different spinal units ranging from no chemical prophylaxis to oral anticoagulation with warfarin and contrasting views on the use of antithromboembolic stockings.	Spinal injuries	Deep	2002	UK
Audit of thromboprophylaxis using Tinzaparin on a random day at the beginning and at the end of the junior house officer's 6 monthly rotation in general surgery. Tinzaparin was appropriately prescribed in 86% and 91% of elective admissions and in 58% and 85% of emergency admissions. The subcutaneous injection of Tinzaparin was commenced on the day of admission in 67% and 75% of patients.	General surgery	Fassiadis	2002	England
Prospective study in 227 consecutive medical inpatients. 38% of 153 risk patients received some form of thromboprophylaxis. 22% of 153 risk patients received adequate thromboprophylaxis.	Medical	Aujesky	2002	Switzerland
Postal questionnaire sent to all consultant surgeons in Scotland (69% response rate). Asked for opinion on best means of thromboprophylaxis. Responses evaluated against SIGN Guidelines. 35% of responses represented under-treatment and 16% over-treatment.	All surgical specialties	Burns	2001	Scotland
An open study of 8,648 admissions to hospital. The overall rate of clinically apparent hospital acquired thromboembolic complications was 0.4% (n = 35). The rate of clinically apparent thromboembolic disease in the high risk group was 2.1% (n = 17). The incidence of thromboembolic problems appeared not to be reduced by prophylaxis, apparently even when stratified by risk group.	All hospital admissions	Wright	1999	England

4.5 Case report of harm with anticoagulants

Report summary	Primary author	Year	Country
Loss of anticoagulant control when miconazole oral gel was used by a patient taking warfarin	Pemberton	2004	UK
A case of spontaneous acute subdural haematoma in the posterior fossa following anticoagulants	Pal	2004	UK
Retroperitoneal haemorrhage during warfarin therapy	Tang	2003	UK
Patient safety, medication error and handwriting	Department of Health	2003	UK
Coroner highlights prescribing error after patient dies from warfarin overdose	Eaton	2002	UK
Retroperitoneal haematoma after paracetamol increased anticoagulation	Andrews	2002	UK
Suprachoroidal haemorrhage after the addition of clarithromycin to warfarin	Dandekar	2001	UK
Deaths associated with warfarin in elderly patients	Reardon	1995	UK

4.6 Cross cutting issues of audit, training and competency

The British Committee for Standards in Haematology (BCSH) guidelines for oral anticoagulants (1998) recommend routine audit of clinic management with review of over-anticoagulated patients as an integral part of anticoagulant services. Review of patient outcome of INR values > 8, or requiring therapeutic interventions to reverse anticoagulant effect are identified as useful criteria for audit. Other audit criteria are also incorporated in the BCSH standards as listed below:

- provision of adequate data for safe transfer of anticoagulant follow-up;
- provision of patient held information (yellow books) on hospital discharge;
- patient information: awareness of need for anticoagulation and possible side effects;
- hospital notes contain information that the patient is currently on an anticoagulant;
- the appropriate use of heparin/warfarin dosage schedules according to BCSH standards;
- follow-up arrangements for patients failing to attend clinic appointments;
- achievement of target INR: 50% of INR's within 0.5 INR units, and 80% within 0.75% INR units of target.

The BCSH also recommend that responsibility for ensuring a safe anticoagulant service and organisational procedure should be documented and a lead clinician should be in charge of the anticoagulant service. Responsibilities of the lead clinician include ensuring that personnel providing anticoagulant services have received adequate training and should be approved prior to commencement of duties.

Published audit data and case reports indicate that there are inadequate competencies of healthcare professionals prescribing, counselling, monitoring and administering anticoagulants.

From the results of the many published audits it appears that the failure to implement published guidelines has been perpetuated by the failure to undertake routine clinical audits in practice and use this data to improve the safety of anticoagulant services. The level of risks of the anticoagulant service are not generally communicated to or known by the clinical governance committees in healthcare organisations in the NHS.

5 From the patient's perspective

5.1 Published reports

Despite well known benefits of using anticoagulants, some clinicians do remain reluctant to initiate therapy, especially for older patients for whom there is an increased risk of haemorrhage. Merli and Weitz (2004) have recently described a 68% risk reduction in primary stroke prevention with warfarin (versus placebo), yet despite this highly significant reduction, fewer than 50% of the eligible patients were treated due to clinician fears of intracranial haemorrhage.

The assessment for prescribing a new drug to a patient should consider both risks and benefits to the patient, and take patient preferences about these into account. However, Protheroe et al., (2000) suggest that taking account of patients' preferences would lead to fewer prescriptions for warfarin than under published guideline recommendations. One small study to investigate the experience and perspective of patients (n=21) does describe their minimal input into the decision to initiate warfarin therapy, instead relying upon the expertise of the clinician (Dantas et al., 2004). However, the same study also describes patients' retention of information regarding their therapy as low, with only half of the sample possessing a superficial level of understanding of the risks and benefits.

Whilst patients generally know the colour of the warfarin tablet(s) they take, less than half may know the strength of their tablets, the reason for taking them, or the effect on their body (Tang et al., 2003). This lack of knowledge and perception of their medical condition reduces further in some ethnic groups. Indo-Asians and Afro-Caribbeans have shown to be significantly less aware compared with white patients ($P < 0.0001$), (Lip et al., 2002).

A lack of knowledge may have other consequences for the safety of the patients, such as under or over-anticoagulation, concurrent self administration of medicines and herbal remedies that might react with their treatment, and no understanding of how to manage missed doses.

Co-administration of warfarin and non-steroidal anti-inflammatory drugs are most commonly associated with clinically significant adverse reactions (Pirmohammed, 2004).

General knowledge as well as specific knowledge about anticoagulants is also required. When studying adult patient anticoagulation control, those with low literacy and numeracy were found to have poor anticoagulation control; patients with lower numeracy levels spent more time above their therapeutic range and had a trend of less time spent in range (Estrada et al., 2004).

Patients and carers who currently, or who have previously, taken or administered anticoagulant drugs were sought to challenge or confirm the perspectives described within these studies. The NPSA would also learn from them about their experiences and coping strategies with anticoagulation therapy, and explore the barriers to safe use.

5.2 Comments and concerns of patient groups and organisations

A total of 156 patient groups and organisations were identified in the database of registered charities using keywords such as anticoagulation, warfarin, heart, atrial fibrillation, stroke, and thromboembolism. Each was contacted by letter to explain the work of the NPSA relating to anticoagulants, and asking for an indication of interest in working with the NPSA via questionnaires and workshops.

Responses were received from 75, of which 46 (61%) expressed a positive indication and desire to be involved with this project. Two questionnaires were subsequently forwarded to the positive respondents. One questionnaire was designed to elicit more details about the group or organisation, the patients they represented, and the role the group or organisation played in supporting their members. The groups and organisations were also asked to forward copies of a second questionnaire to their members. This aimed to identify patient demographics, knowledge and numeracy skills. Finally, both questionnaires requested an indication of interest in attendance at a one day workshop aimed at exploring patient experience in greater depth.

Completed questionnaires were received from 22 organisations and 45 patients and carers.

Organisational responses

- 19 (86%) declared membership to include the frail and those over 70 years;
- 18% had members whose first language was not English;
- three (14%) did not believe that sufficient information was provided to patients when they first started anticoagulation therapy; specifically that information must be reinforced, more help should be given to those at risk patients (older people and non-English speakers), and more information about side effects;
- 18% provided information to their membership about anticoagulants, two via meetings and two through supply of the British Heart Foundation booklet.

Patient responses

Age ranges of respondents: Under 18 (2); 18 – 60 (11); 60 – 70 (13); and over 70 (19). 39 (93%) were white, one Asian, one black, and one mixed race.

The majority (38) had been taking anticoagulants for more than one year, although five had taken them for less than a year, and one for less than four weeks. Atrial fibrillation (26%) and heart valve replacement (23%) were the most common indications for use. One patient recorded that they did not know what they took anticoagulants for. Treatment had commenced for the majority (91%) in hospital, and all but one patient had been provided with information about anticoagulants and the need for regular blood tests. However three (7%) did not understand the information they received.

INR tests were conducted in the GP surgery (36%), at the hospital clinic (19%), other or multiple locations (18%), and one patient self tested at home. INR results and necessary dose changes were communicated to the patients via a number of routes: hospital or surgery writing into the monitoring book (49%); and phone call, letter or e-mail (46%). Of these responders, only four did not hold a monitoring book. One further respondent self tested and recorded the result from their equipment, and one respondent stated that, "nobody tells me about my results or my dose".

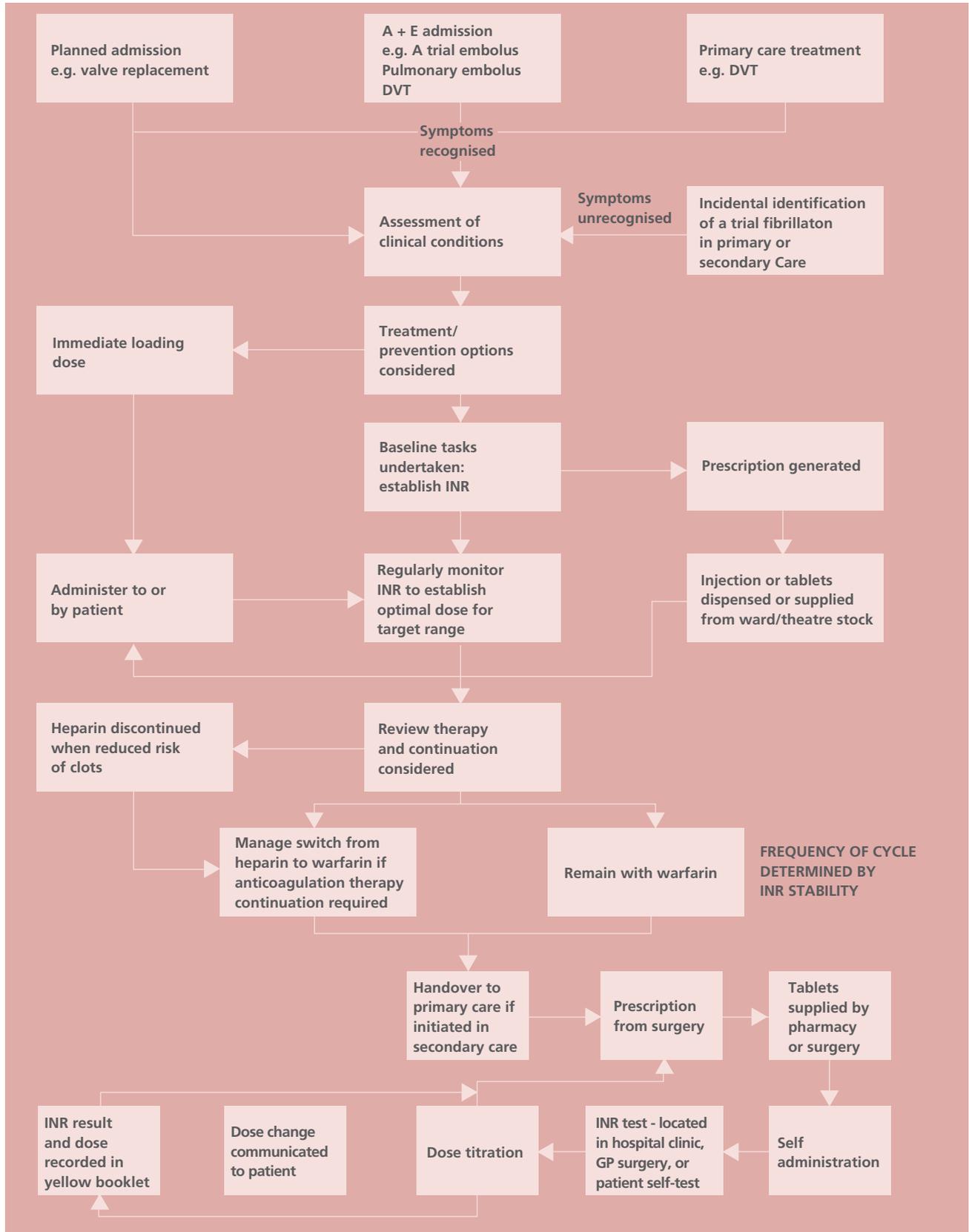
Patients taking warfarin were asked to record the tablet strengths they took (colours of each were described in the questionnaire), and also whether they had any problems in working out how many or which combination of tablets to take if their dose was changed. Eighteen held a single strength of warfarin, and 22 had combinations of two or three different strengths. One patient did not know what strength tablets they had. Six respondents stated that they had difficulty working out their dose and a further four had someone else complete this task for them.

Whilst the sample size is small compared to the total number of patients receiving anticoagulation therapy, the responses to the questionnaires do reflect a level of commonality with the published literature on knowledge and numeric ability potentially affecting safe use of anticoagulant therapy.

A pathway (Figure 3) of the routes patients travel within the healthcare system when in receipt of anticoagulation therapy was developed as an aid to the patient workshop. The intention of this was to help guide discussions and to identify any common points along the pathway where patients encountered barriers or difficulties to safe medicine use.

In discussion the 18 participants (self selected from the questionnaire respondents) agreed that the pathway was a reasonable representation of their personal experience. The principal difficulties for patients and carers lay not so much in the pathway itself as in the information and support provided outside the occasional consultation. A full report of the workshop is contained in Appendix iii.

Figure 3: Process map of the patient pathway of the use of anticoagulation in primary and secondary care



5.3 Key outcomes from the patient workshop

Process steps for anticoagulation therapy		Patient experience and barriers to safe use
1	Decision to treat	Wide range of experiences and involvement; use of medical jargon and abbreviations unhelpful. Lay knowledge of warfarin is as 'rat killer' and this use needs to be described in context of patient anticoagulation for some.
2	Document and communicate diagnosis and treatment plan	Problems with information not communicated to patients' GPs. Poor communication with carers. Stroke patients receive less information and support than others. No planning for coping during first four weeks post-discharge, nor for longer term regarding schooling, holidays, and other social events. Lack of information about effect of foods and alcohol on anticoagulation control. Overall discharge is the weakest yet most critical stage.
3	Arrange monitoring	Generally good although some do not understand INR. Lack of clarity about what the readings mean, especially when they vary between tests.
4	Prescribe	Lack of communication between hospital consultant/clinic and GP when new drugs are introduced – other prescribers can be unaware of this. Conflicting information about aspirin; some are prescribed whilst others are told to avoid – the reasons for this need to be explained. Conflicting advice is a source of anxiety – patients do talk to one another and compare treatments.
5	Prepare/dispense/supply	Some patients do not trust the system where they receive different packaging on each prescription supply. Whilst most are aware that warfarin tablets are colour coded, different manufacturers' packaging (primary and secondary) causes a degree of anxiety that they have received the correct medication. At discharge it is vital that patients know to request further supplies before the TTO supply runs out; reinforcing information and testing patients' understanding.
6	Administer dose	Use of 0.5mg warfarin tablets is not widespread yet many patient and carers need to break 1mg tablets to produce the correct dose. Local policy of only using 3mg, and then prescribing 2mg daily dose causes very real problems for patients; local policies must be able to respond to patient need. Alternate day dosing regimes are difficult especially for those with poor memories.
7	Monitor treatment	Home testing, especially for children to avoid regular loss of school time, appreciated by patients but not by clinicians.
8	Discontinue treatment	Dentists appear to be unaware of the specific needs of patients receiving anticoagulants and undertake treatment (from hygiene to multiple extractions) without managing the treatment or referring to others.
9	Communication with patients/use of yellow book	The yellow book is an essential part of the process but GPs do not ask to see it. There is a lack of good liaison between the NHS and schools, particularly around participation in sports, school trips, and likelihood of bruising. The NHS should accept that patient groups form part of the pathway and can help patients when first diagnosed and throughout their anticoagulation therapy as a source of support.

6 Risk assessment

The 'structured what-if technique for hazard identification' (SWIFT) is good for considering human and organisational factors that may affect safety. The technique is a structured brainstorming approach, supported by a prepared checklist of issues that may be relevant to the study. The intention of the SWIFT exercise is to identify as many risk factors as possible concerning the current use of anticoagulant therapy, then repeat the process to see how risks may change with the introduction of the proposed safety solutions.

6.1 Anticoagulant therapy process maps

Generic process maps were identified to assist with the comprehensive examination of current and potential risks associated with the use of anticoagulants. Three stages were identified: stage 1: induction of treatment; normally undertaken in hospital (Figure 4); stage 2: hospital discharge stage (Figure 5); stage 3: a maintenance stage, normally undertaken when the patient is in the community (Figure 6). A decision to discontinue therapy can be made at any time in the three stages of anticoagulant use.

Figure 4: Induction/inpatient



Figure 5: Patients about to be discharged from hospital

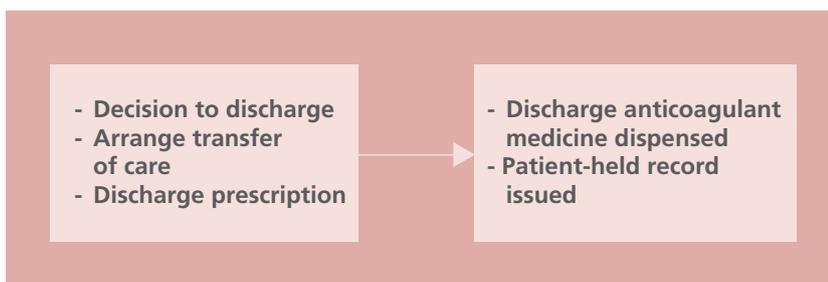
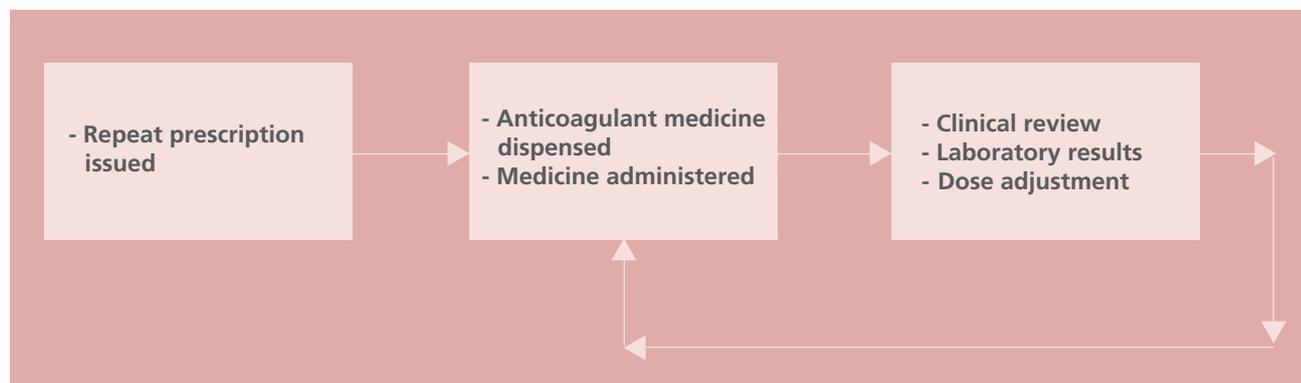
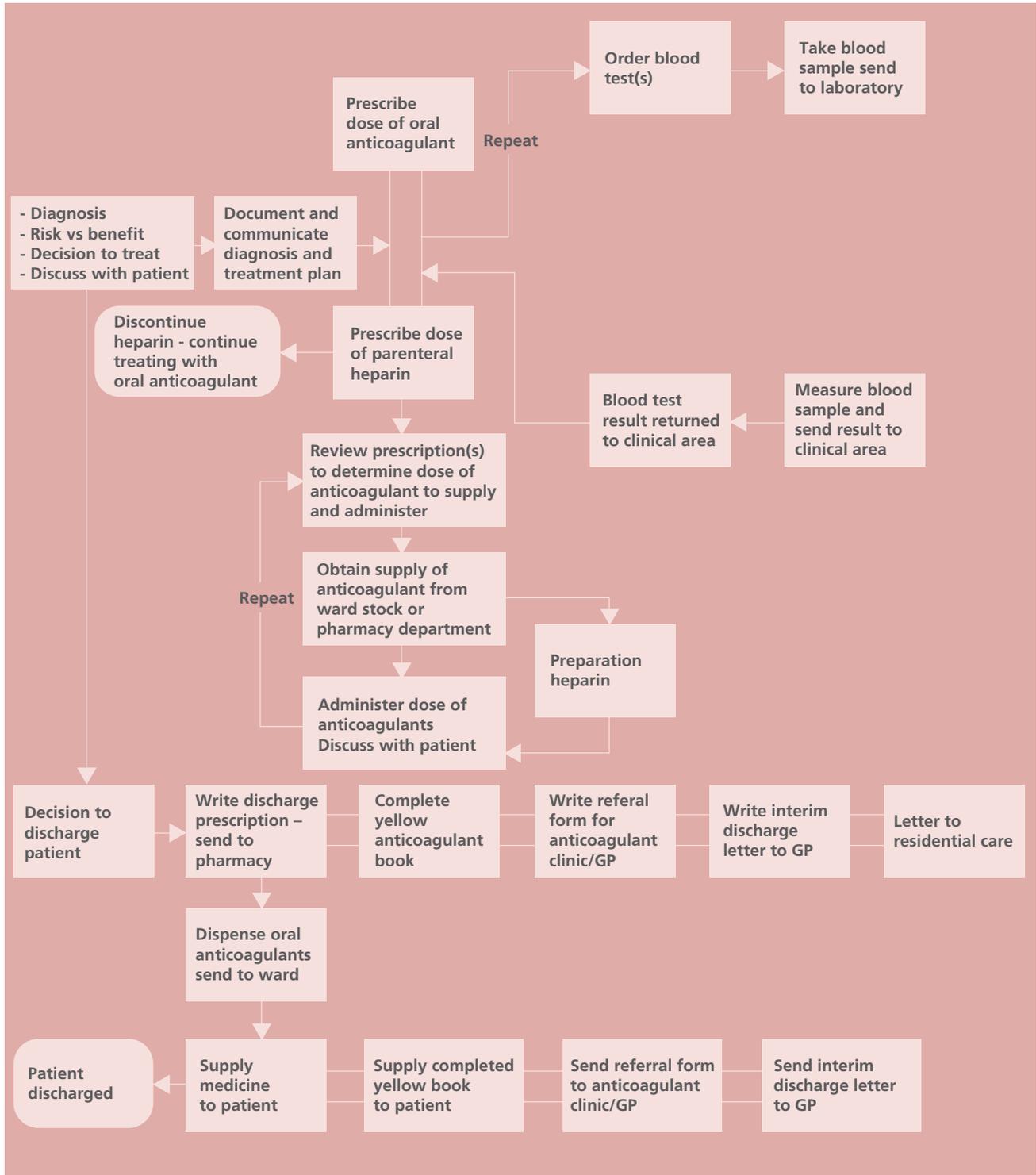


Figure 6: Patients on maintenance anticoagulant therapy in the community



The process of use of anticoagulant products can be complex, particularly when the patient is in hospital; when injected and oral anticoagulant products are used together for a short time; and when multiple tasks are required to ensure continuity of care prior to discharge from hospital. More detail concerning stages 1 and 2 for hospital inpatients is shown in Figure 7.

Figure 7: Process map for hospital inpatients



6.2 Risk assessment matrix

A risk matrix was developed to assist in allocating scores during the risk assessment process. The risk matrix was reviewed and amended by the clinical risk groups as part of the SWIFT process.

Projected incidences of harm per year in the UK						
6	20,000	Medium	High	High	High	High
5	~2,000	Medium	Medium	High	High	High
4	~200	Low	Medium	Medium	High	High
3	~20	Low	Medium	Medium	Medium	High
2	~2	Low	Low	Low	Medium	High
1	Improbable	Low	Low	Low	Low	Low
		A	B	C	D	E
	Estimated clinical consequences to the incidents	Negligible: little or no effect	Marginal: leads to medium term harm	Critical: causes severe harm	Fatality	Catastrophic: causes two or more fatalities

6.3 The definitions of risk consequences used in the risk matrix

Risk consequence	Definition
Negligible: little or no effect	This is an unexpected or unintended incident, which required extra observations or minor treatment and caused minimal harm to one patient.
Marginal: medium term harm	This is an unexpected or unintended incident, which resulted in further treatment, cancelled treatment, transfer to another area, possibly critical care, and which caused short term harm to one patient.
Critical: causes severe harm	This is an unexpected or unintended incident, which caused permanent or long term harm to one patient.
Fatality	This is an unexpected or unintended event that caused death for one person.
Catastrophic: causes two or more fatalities	This is an unexpected or unintended event that caused death for two or more patients.

6.4 Risk assessment team members

A multidisciplinary team from the NHS assisted the NPSA with the risk assessment. Four full-day risk assessment workshops were held. Details of group members are included in Appendix ii.

7 Results of the risk assessment process

7.1 Summary results

66 individual risks were identified for the current systems for using anticoagulants. Of these risks 24% (16) were rated as high risk, 55% (36) medium risk and 21% (14) low risk. The steps of the anticoagulant use process associated with the greatest number risks were the prescribing and dose administration steps.

Details of all 66 risks and their scores are provided as a separate document that can be downloaded from www.npsa.nhs.uk

No.	Process steps for anticoagulant therapy	Risk scores for current practice			
		Low	Medium	High	Totals
1	Decision to treat	1	1	4	6
2	Document and communicate diagnosis and treatment plan	1	1	1	3
3	Arrange monitoring	1	4	1	6
4	Prescribe	5	10	8	23
5	Prepare/dispense/supply	1	3	2	6
6	Administer dose	2	8	0	10
7	Monitor treatment	2	5	0	7
8	Discontinue treatment	0	3	0	3
9	Communications with patients	1	1	0	2
10	Totals	14	36	16	66

7.2 High risks

A list of 15 high risks was developed from the risk assessment exercise, incident data, published reports and professional networks. Developing safer practice solutions to minimise these risks is predicted to reduce the number of deaths and harm resulting from the use of anticoagulants. Details of these 15 risks are provided below:

- 1 Cross cutting issue:
Inadequate training and work competencies of some staff who prescribe and monitor anticoagulants.

- 2 Cross cutting issue:
Inadequate clinical audit of anticoagulant service and/or failure to act on audit results to improve the service.

- 3 Failure to initiate anticoagulant therapy (including thromboprophylaxis) where indicated.

- 4 Poor documentation of reasoning and treatment plan at commencement of therapy.

- 5 Prescribed wrong dose or no dose of anticoagulant (especially loading doses).

- 6 Unconsidered co-prescribing and monitoring of non-steroidal anti-inflammatories and other interacting medicines.

- 7 Incorrect selection, preparation and administration rate of heparin products.

- 8 Unsafe arrangements and communications at discharge from hospital.

- 9 Insufficient support and monitoring of warfarin therapy for the first three months and for vulnerable groups.

- 10 Inadequate safety checks at repeat prescribing and repeat dispensing in the community.

- 11 Confusion over anticoagulant management for dentistry, surgery and other procedures.

- 12 Non-standardised supply/use of 0.5mg, 1mg, 3mg and 5mg tablets.

- 13 Yellow book, patient-held information in need of revision and translation into other languages.

- 14 Inflexible medicines presentations and arrangements in care homes to implement anticoagulant dose changes.

- 15 Inadequate QA for near-patient testing equipment.

8 Potential safer practice solutions

8.1 Published reports of potential safer practice solutions

A comprehensive literature search for safer practice solutions from the UK or of relevance to UK practice was undertaken. A summary of these solutions is detailed below and details of the specific publications are included in the 'References' section of this report:

- audit of process and outcome indicators for anticoagulants (five guideline references and 17 audit references);
- audit of patients selected for thromboprophylaxis (nine references);
- use of computer dosing software for decision support and audit (four references);
- better designed inpatient monitoring/prescribing/administration charts (one reference);
- use of pharmacists and nurses to provide anticoagulant service, especially for hospital inpatients – improved links between inpatient and ambulatory services (41 references);
- GP managed anticoagulant services (five references);
- improved communication when patients discharged from hospital (five references);
- safety alerts/reminders for anticoagulants (six references);
- support and monitoring of patients in the first three months of warfarin therapy and for vulnerable groups and redesign of patient-held information (16 references);
- near-patient testing of anticoagulants (six references);
- self management of anticoagulant therapy by patients (10 references);
- managing anticoagulation for dental, surgical, endoscopy and other procedures (seven references);
- ready to use presentation and standardised method of use of unfractionated heparin products (four references);
- new anticoagulants – melagatran, ximelagatran and fondaparinux (14 references).

8.2 Additional safer practice solutions identified by the risk assessment process

Analysis of the risk assessment data identified the need for four additional safer practice solutions not included in the published literature to date:

- ensure adequate training and work competencies for all staff who prescribe and monitor anticoagulants;
- standardise the way doses are prescribed/supplied;
- clarify safety checks for GP prescribing repeat prescriptions of anticoagulant products and of pharmacists supplying anticoagulant products;
- review methods for anticoagulants that are supplied and administered in care homes.

8.3 Safer practice solutions not taken forward by the NPSA

Each potential solution was reviewed for its applicability in different settings, ease of use and cost of implementation, and whether other agencies were taking work forward.

The newer anticoagulants

The newer anticoagulants clearly have the potential to significantly improve the ease and safety of anticoagulant use. However, the clinical indications and use of these products is still subject to clinical trial research and are under consideration by the Medicines and Healthcare products Regulatory Agency (MHRA) and National Institute for Health and Clinical Excellence (NICE). As these other agencies are undertaking the evaluation of these products, and are unlikely to completely replace the use of warfarin and heparin products in the near future, the NPSA has decided not to include the use of these newer anticoagulants in the list of safer practice solutions to be further developed and recommended to the NHS. However, reference will be made in the final NPSA publication to current and future evaluations and guidance concerning these newer anticoagulants from these other UK agencies.

GP anticoagulant services, near-patient testing and patient self management

The NPSA is aware of benefits to certain patient groups from the provision of all three types of service. However, only a minority of patients receive these services and there is insufficient evidence that these types of services provide safer care compared to traditional anticoagulant services provided by hospitals, or that patients would choose to receive these services in preference to more traditional means of delivery. For these reasons, these three safer practice solutions were not included in the NPSA list for further work.

Patients selection for low dose thromboprophylaxis with low molecular weight heparin

There is evidence that a significant number of patients in medical and cancer areas, as well as surgical areas, who have appropriate risk factors do not receive thromboprophylaxis with low molecular weight heparin products and a percentage of these patients experience thrombotic events and experience harm or death as a result. This topic was the subject a Parliamentary Health Committee report in 2005. NICE is currently undertaking a review of thromboprophylaxis and will issue guidance on this topic in due course. The NPSA has decided not to include methods to improve the use of thromboprophylaxis in patients with risk factors, as this is being taken forward by NICE. However, reference will be made in the final NPSA publication to NICE recommendations on this topic.

8.4 Safer practice solutions to be further reviewed and developed

- 1 Ensure adequate training and work competencies for all staff who prescribe and monitor anticoagulants.

- 2 Regular monitoring of safety indicators for inpatient and ambulatory anticoagulant services and results sent to trust clinical governance committees.

- 3 Improved guidelines:
 - loading doses;
 - patients going for dental, surgery, cardioversion, endoscopy;
 - QA for near-patient testing.

- 4 Promote the use of computer dosing software for decision support and audit.

- 5 Use of pharmacists and nurses to provide anticoagulant service especially for hospital inpatients – improved links between inpatient and ambulatory services.

- 6 Improve communication when patients discharged from hospital.

- 7 Improve safety alerts when interacting medicines are being prescribed.

- 8 Improve support and monitoring of patients in the first three months of warfarin therapy and for vulnerable groups.

- 9 Clarify the role of the GP prescribing repeat prescriptions of anticoagulant products and of pharmacists supplying anticoagulant products.

- 10 Revise design and content of patient-held record.

- 11 Standardise the way doses are prescribed/supplied.

- 12 Standardise the presentation and method of use for unfractionated heparin products.

- 13 Review methods for anticoagulants that are supplied and administered in care homes.

- 14 Improve the design of forms/software for prescribing, monitoring and administering anticoagulants.

8.5 Risk assessment scores with possible safer practice solutions

The identified risks discussed in section 7 were re-scored with the possible safer practice solutions listed in section 8.4, assuming all the possible safer practice solutions were implemented by the NHS. The risk scores changed; high risks reduced from 24% (16) to 5% (4), medium risks remained the same at 55% (36) and low risks increased from 21% (14) to 40% (26). This analysis supported the further review and development of the safer practice solutions.

No	Process steps for anticoagulant therapy	Risk scores for current practice				Risk scores for proposed practice			
		Low	Medium	High	Totals	Low	Medium	High	Totals
1	Decision to treat	1	1	4	6	1	1	4	6
2	Document and communicate diagnosis and treatment plan	1	1	1	3	1	2	0	3
3	Arrange monitoring	1	4	1	6	1	5	0	6
4	Prescribe	5	10	8	23	7	16	0	23
5	Prepare/dispense/supply	1	3	2	6	2	4	0	6
6	Administer dose	2	8	0	10	6	4	0	10
7	Monitor treatment	2	5	0	7	6	1	0	7
8	Discontinue treatment	0	3	0	3	0	3	0	3
9	Communications with patients	1	1	0	2	2	0	0	2
10	Totals	14	36	16	66	26	36	4	66

9 Next steps

Using risk assessment methods, comprehensive literature review, site visits and professional networks, the NPSA has prioritised high risks and a number of possible safer practice solutions for anticoagulant use.

The NPSA is further clarifying, developing and piloting safer practice solutions with stakeholders to enable us to prepare draft recommendations for a wide stakeholder consultation in the first quarter of 2006.

The NPSA intends to publish final recommendations in the second quarter 2006.

We intend to formally evaluate the implementation and outcome of the safer practice recommendations in 2007.

Appendix 1: Membership of the external reference group

Member's name	Designation	Representing
John Scarpello	Consultant Physician	Royal College of Physicians
Frank Milligan	Nurse Adviser	Royal College of Nursing
Dr Gerry Dolan	Consultant Haematologist	Royal College of Pathology
Dr Rhona McLean	Consultant Haematologist	Haematology
Dr John Luckit	Consultant Haematologist	Haematology
Sarah May	Executive Head of Strategy	Medical Laboratory Scientific Officers
Kate Willis	Coagulation Nurse Specialist	Coagulation Nurse Specialists
Andrea Molyneaux	Senior Medical Device Specialist	MHRA - in vitro diagnostics
Jackie Hough	Phlebotomy Manager	National Association of Phlebotomists
Amanda Powell	Senior Clinical Pharmacist	Hospital Pharmacy
Neil Gammack	Deputy Chief Pharmacist	Hospital Pharmacy
Professor David Fitzmaurice	Professor of Primary Care Research	Royal College of General Practitioners
David Morgan	Surgical Specialty Adviser	NPSA Clinical Specialty Adviser Surgery
Nihal Gurusinghe	Honorary Secretary	Consultant Neurosurgeon
John Thompson	Consultant Vascular Surgeon	Vascular Society
John Hall / Noel Dixon	Community Pharmacists	Community Pharmacy
Sue Wooller	Senior Clinical Pharmacist	Hospital Pharmacy
Dr Jonathan Wilde	Consultant Haematologist	MHRA – anticoagulants
Steven Davidson	Specialist Haematology Nurse	CLOT (Clinical Leaders of Thrombosis)
Dr David Whillier	General Practice	General Practice
Gillian Nother	Nurse Adviser	Care Homes sector
Carly Groom	Staff Nurse Acute Assessment Unit	Staff Nurses
Professor David Cousins	Head of Safe Medication Practice	NPSA
Wendy Harris	Senior Pharmacist	NPSA
Georgina Fletcher	Human Factors Specialist	NPSA
Mark Boulton	Risk Management Adviser	NPSA
Linda Matthew	Patient Safety Manager	NPSA
Jean Lowe	Patient Safety Manager	NPSA

Appendix 2: Report of the patient workshop

Preventing patient safety incidents with anticoagulants: a patient workshop, 17 March 2005

1 Introduction

This is a report from a consultation with patients using anticoagulant drugs, which explores their experience with the patient pathway. In all, 12 patients and four carers took part in the discussion, as well as two people from organisations working on behalf of people taking anticoagulants. Of the patients, seven had experienced a stroke, four had heart problems and one had had a pulmonary embolism. Two carers accompanied stroke patients (often speaking on their behalf, due to communication difficulties) and two were parents of children with heart problems.

The report does not recount the discussion in chronological order but describes some general themes raised in the course of the day. It should be added that the number of people attending enabled them to have a good discussion about key issues but one cannot draw statistical inferences from any of the comments made.

2 First plenary

Wendy Harris, Senior Pharmacist at the NPSA, welcomed the participants and explained that although the principal purpose of the day was to help the NPSA learn, she hoped it would also prove helpful to them. She introduced Peter Mansell, the NPSA's Director for Patient Experience and Public Involvement, along with the facilitation team and noted that the latter were fully independent from the NPSA. All discussions would be completely anonymous.

Wendy and Peter explained that the NPSA uses a technique known as root cause analysis (RCA) to learn about problems and potential solutions to help improve the safety of patients in the NHS. The remit includes issues that may be addressed nationally or locally, and new ideas are tested before being implemented.

Roughly half a million people are taking anticoagulants, mostly warfarin. Certain groups seem to be at particular risk: older people; those who drink a lot of alcohol; those new to taking the drug; and those who are given it by a family member or care worker. In fact, more people should be taking anticoagulants if everybody who is at risk of DVT or pulmonary embolism were identified. There are therefore issues of identifying those who should be taking these drugs as well as issues of ensuring their safe administration, including testing, dose changes and how they affect patients and their families.

The NPSA is taking a particular interest in anticoagulants. It has reviewed the literature on the subject, both in the UK and beyond. It has held discussions with clinicians and, with their help, developed a map of the path patients follow in the course of treatment, termed a patient pathway. This assumes that patients are diagnosed either because they have been taken into hospital or by a GP, that their situation is assessed, treatment options considered and baseline tests undertaken with a decision then made; patients are given the appropriate dose, with a cycle of regular checking. The NPSA is keen to understand whether it works in this way in practice and whether any difficulties are experienced along the way.

3 Group discussions

All participants had been provided with a printed sheet setting out the patient pathway on which they were invited to comment on how it fitted with their own experience. Roughly half of the participants completed these, with their contributions suggesting that the pathway generally made sense to them. In discussion it was said to be a reasonable representation of their routes to treatment. There were some sceptics, however, with one participant commenting:

“The NHS this year has paid out £360 million in negligence claims for anticoagulation. So why are they paying out if clinicians are doing it this way? Clearly they’re not!”

The discussion highlighted a number of areas where patients had experienced difficulties but it should be stressed that participants tended to speak highly of the NHS:

“Our national health service locally is fantastic. Our local hospital has got a special stroke ward where all these things are discussed, so we’re more than happy with our area facilities.”

“There seems to be general assumption that anticoagulant treatment is badly done. Mine is extremely well done. It is brilliant.”

The principal difficulties for patients and carers lay not so much in the pathway itself as in the information and support provided outside the occasional consultation. A few also recounted specific incidents where patient safety was an actual or potential problem. These issues are best explored in terms of the different stages of the pathway.

4 Diagnosis

The initial recognition of the need to take anticoagulants did not seem to be much of a problem for most participants. They described various routes to discovering this need:

“I fell off a chair at work; they didn’t know what it was, because I wasn’t suffering any chest pains or shortage of breath.... It was only when I was put in the cardiograph at the hospital that they realised I was having a heart attack. Then I went through that system okay.”

“I had a coronary bypass operation and we were in a routine check up a month later when they realised the scarring had caused atrial fibrillation; it was at that stage I was then put onto a different drug to start with and then warfarin.”

Many had been put on anticoagulants whilst in hospital, sometimes before they were fully aware of their situation:

“You’ve already been given the warfarin long before you even know what day it is. I was in a coma for a week so, by that time I was already on warfarin.”

5 Understanding anticoagulants

The big issue around the time of initial diagnosis and treatment was obtaining information on anticoagulants. There was a substantial range of experiences, with some being given all the information they could want and some being given none at all. Difficulties could arise where patients were unable to take in information. One participant said:

“When you’re first taken ill, your mind’s not open.”

Moreover, doctors tended to speak in their own language:

“The hospital staff tend to use abbreviations, ‘oh yes, this is a TLC’ or something like that. So you haven’t got a clue what they’re talking about – yet they carry on because it’s common language to them.”

A key point in the process is when patients are discharged from hospital; this is a time when the enormity of their situation can hit home, together with an awareness that they will no longer have ready access to doctors:

“When you’re in hospital, you’ve got clinicians watching what’s happening. It’s the day you leave hospital when suddenly it’s you that’s doing it, and you that’s got to look after yourself – and that’s when the problem comes.”

“People who are discharged from hospital are given so much information in such a short time that half of it goes over their head. They’re not worried about what pill they’re going to take – they’re worried about how they’re going to manage at all.”

In some cases, the consequence of a lack of information was very severe. One participant ended up having a second stroke because he did not understand the importance of continuing to take the drugs:

“When I had my first stroke and they give you the tablets... I never knew I was supposed to take them all the time. No one discussed it with me.”

Some, however, also recounted very good experiences:

“I had been very well briefed on what it would be like, what to expect, what to do. I wasn’t kicked out the door with a ‘cheerio’.”

6 Testing

The anticoagulation testing (known as INR testing) process seemed to vary. Some patients had it done at their general practice, but most seemed to go to their hospital. Some obtained the results more or less immediately, some on the same day after a wait, and some had a delay of some days. Most participants said that their arrangements worked fairly smoothly:

“The result is available there and then and the dose is adjusted there and then if necessary. I have got a yellow book and they sign it – it is brilliant.”

“The nurses are quite good up at the anticoagulant clinic – if my son is too low, they will phone me straight away and say ‘double his dose for this evening.’”

There were some complaints where there was an extensive wait on the day to get the results. In one group there was concern that the results of testing were not always subject to rigorous analysis. One participant said:

“It’s a tick the box, the patient’s been seen.”

Most participants seemed to understand the significance of attending the tests, together with the variation in frequency:

“It is a stable situation now, we only go every couple of months.”

The test itself was seen to cause little difficulty:

“it’s a finger prick.”

One or two had a more old fashioned hypodermic. A few disliked it:

“a wasp sting in my thumb, which I complain about.”

One father suggested that attention should be given to the size of needles used with children. One participant expressed slight concern that there was no second opinion:

“It’s putting too much responsibility on the person who’s taking the reading.”

But there was a general agreement that the testers were very good. One participant noted that the process was expensive for the NHS:

“they’re telling 90% of the people, ‘you’re OK, keep taking the medicine’, which seems a waste of a valuable information resource.”

There was some concern about the need for patients to tell the person testing them that they were unwell:

“it’s up to you to say you’re not feeling well or something is wrong, because until you open your mouth and say that, nobody knows.”

Some patients might not know that they should do so, and, if they were stroke patients, might not be able to do so effectively because of language problems or general depression:

“As patients we need to take responsibility. But we also need to recognise that sometimes you’re not going to be in a position to take responsibility. The very reason you’re there is because you’re not well.”

Most participants seemed to understand what INR stood for and its significance, but at least two people asked what it meant.

Some expressed a lack of clarity about why their readings varied. When they had questioned them, several had been told that they were ‘sensitive’, which was not felt to be very illuminating. One participant had a query about the establishment of his therapeutic range; he wanted to ask the doctor who had set it in the first place, but that doctor had died. Another, looking at that participant’s yellow book, thought that the fact that he was outside this range more than half the time required some investigation.

7. Recording the results

The yellow book was clearly seen as an essential part of the testing process, as it was the means by which information was passed on to key people. The system for completing this book seemed to vary. In some cases, it was filled in immediately, but in others it was taken to the hospital by the person taking the blood at the GP surgery and then posted back with the next appointment. Some liked the idea of the hospital completing the book and saw this as a fail-safe. The importance of the yellow book was well recognised:

“It’s important that you take this book when you’re admitted to hospital or if you have an accident. Somebody needs to give it to somebody before they start sticking anything into you.”

It was said more than once that the participants’ GPs did not always know that their dose had been changed by the hospital, and the yellow book was therefore essential for passing on such information.

Participants tended to carry their yellow book with them at all times:

“It’s in mum’s bag, 24/7.”

In one group, discussion of this issue gave rise to the spontaneous suggestion of an electronic patient record on a swipe card, which could be used in any hospital, GP surgery or dental practice. This was widely supported, given the importance of the information:

“It’s in your own interests that all your details are on file, so if you can’t speak or you have an accident and you’re unconscious, then you know as soon as you get there that they’re going to have your name in a computer – and there it is, warfarin, and other medications you’re on.”

One man active in his support group had found that a number of members did not have a yellow book and wondered whether its importance had ever been explained to them. It was suggested that this should be stressed at the initial interview and that all doctors, including GPs, should ask to see the book, although they did not in fact do so:

“I have never been asked for mine except at the hospital.”

Some discussion centred on other means of identifying patients taking anticoagulants. One man stated that he had purchased an identification bracelet; another spoke of wearing a talisman with information about the drugs he was taking, in case he was taken ill on the street. It was also important to have systems in the home for others to know about medication. One participant had a folder from the hospital with such details; another spoke of a small green bottle that was kept in the refrigerator or cupboard, with a copy of all prescriptions:

“If paramedics come in, they would be able to pinpoint very quickly your condition.”

8 Home testing

Only one adult and two children had home testing machines, the latter provided by the Children's Heart Federation, where a family was felt able to use them. This was primarily to avoid the loss of school time on a regular basis. Neither child was yet using the machine; one family, however, was waiting for training and the other was having considerable difficulty obtaining the testing strips from their GP. This was the cause of some concern, as both the hospital and the GP argued that this was the other's responsibility:

"The NHS is very good, but it is not synchronised. It's really confusing."

A representative from the Children's Heart Federation brought some forms to the meeting, completed by parents whose children had been provided home testing machines. These suggested that there were enormous benefits for the family, saving considerable time previously spent travelling to the hospital and making possible a more homely atmosphere for the tests:

"She is much calmer with me doing it."

They also enabled the family to go on holiday more easily. Some children also offered comments:

"I don't have to take time off school – it makes my life more normal."

"I don't have to suffer the pain of having blood taken."

"I don't like going to the clinic with all the old people there."

The adult with the machine, bought expensively from the US some years ago, said he felt that he got the information much more quickly than he had before:

"I usually self test... If you have your blood taken today, it's three or four days before you know what your INR is and then there can be delays if the clinician is changing your dose, whereas I change my own dose and it's an instant result."

He noted that the hospital doctors did not trust the machine:

"They thought it was voodoo."

Even his consultant could not believe that he was undertaking his own INR tests. They initially forbade him to use it on the ward when he was in hospital, but he was insistent because it enabled him to get his results immediately. The same man also argued that at a bed cost of £800 per night at his hospital, having a machine on each ward would save £18,000 per year, because it would eliminate the need for patients to wait in hospital from Friday to Monday for their results.

A few participants liked the idea of self testing as it would save their own and hospital time:

"It would save the NHS quite a bit of money."

It was suggested that they would have confidence to cope with this, especially if there was a clear back-up system for checking elsewhere if the reading suggested that something had changed. Alternatively, there could be a regular central test, to provide a check:

"Just to make sure you're on the right dose."

9 Taking the drugs

Most participants experienced relatively few difficulties in coping with the medication. Nor was there much confusion about the correct dosage, although there was some surprise at the different dosages taken by different patients. This information was provided in the yellow books and participants generally felt that they had a good system for understanding any necessary changes:

“The doctor knows what your dosage should be; mine has to be between 2.9 and 3.4; the doctor will work on that, but if it goes up to 3.5, then he will turn round and say ‘come back in ten days and we will check it’. So from my point of view, the relationship is good.”

Where the issue was discussed, participants also knew what to do if they missed a dose. On the other hand, there was some concern about confused elderly people being left to cope on their own.

One difficulty was having the right strength of tablet when there was a need to change a dose at short notice. One carer, for instance, said he had to break a pill because he was told to give 2mg, but only had 3mg pills:

“You are stuck, aren’t you? You have to be thinking of breaking a pill.”

Another participant said that she always had both 1 mg and 3 mg tablets to overcome this problem. One woman had been told to take half a milligram only to be told that the hospital did not supply this, because there was little call for it.

A few expressed concern about changes in the colour or other characteristics of pills, including their packaging, due to changes of brand. This could create anxiety that they had the right medication:

“Some people worry that they’ve got the right one, particularly if they’re having it delivered to their home.”

Some patients even referred to their pills by the brand name, as it was prominent on the box. People preferred continuity, especially where they were conscious that pills were colour coded by strength. On the other hand, patients could end up simply trusting the system:

“I can’t name the brand, because for about six months they kept on changing it. In the end I gave up and I said well, they must be right, so I just open it now and see what colour they’ve given me.”

Some participants felt it could be difficult to remember to take their medication. A few used dated pill boxes to help them, especially when they took other medication as well. This was sometimes a problem for people with a stroke, because of physical difficulties. One participant noted that it was more difficult to remember medication if it was prescribed to be taken every other day. Another wondered whether it mattered whether the pill was taken in the morning or evening; several said they had been told to take it in the evening, as blood tests were given in the morning.

The two parents of children taking anticoagulants generally felt that they were very good at taking them, although there were other worries associated with the medication. One mother worried when her son was away, for instance on a school trip; she had him tested beforehand and would give the teachers the correct amount. Playing games at school was a source of concern, although his friends were aware of his taking anticoagulants. There were also worries about the future, when her son would begin to go to parties. One father commented:

“For the first three years, we were giving four or five medicines a day. Every second we did not let our son out of our sight. Three years he didn’t sleep well. So after that operation, it changed the world – my son is okay and he’s going to school and everything.”

It seemed that most participants had been told that they would be on warfarin for life. This was accepted:

“I’ve always taken the view that I’m alive, so I’m ahead of the game. If you’re given a second life as it were, you just accept what goes with it.”

The one difficulty here was accepting it in the first place:

“warfarin was rat poison to me.”

10 Day to day management of anticoagulants

Although the patient pathway provided was felt to cover patients’ experiences when they were in contact with the NHS, it did not address problems which arose when they were not. This is very important to patients, as there are many queries and uncertainties which can arise during this time.

11 Concerns about anticoagulants

Eating certain foods was raised as an issue in every group. One man, for instance, discovered that he had been eating too much fruit and vegetables nine months after he had first been on warfarin:

“I thought there’s something wrong here, because I couldn’t stabilise: one day the blood was thin, the next minute it was thick. The specialist said it will balance out ... well, I would not have just carried on taking the fruit and veg if I’d have realised why.”

He queried why this was not made clearer in the information provided with warfarin.

Several participants mentioned that they were not supposed to drink cranberry juice, but suggested that such knowledge was not widespread:

“When we brought this up at our support group, there were 65 people there and nobody knew.”

One participant only learned because a nurse saw her about to drink some in hospital. Another said that her mother’s INR was very unstable for no reason that was ever explained, but on hearing about cranberry juice wondered if this were the cause.

The extent to which drinking was allowed was not discussed quite so much, but seemed somewhat unclear. One man was told that binge drinking was out of the question, but regularity was okay.

A more worrying problem arose around other drugs participants were taking. Several felt very uneasy on this issue, being aware that such drugs had notices about checking with a doctor if they were taking warfarin:

“You assume that your doctor has got other medication under control. When you see the consultant, they will decide what your medication is, then write to your GP, but you are like the piggy in the middle – you don’t know.”

“Mum’s INR goes up and down like a yo-yo. They say she is ‘sensitive’ and I keep saying, ‘is it sensitive, because she is taking five other medications?’”

Aspirin was a particular source of anxiety, because people were given conflicting information. Several participants said that they had been told to take it, whereas others had been told to avoid it:

“The only one I have ever been told was, ‘don’t take anything that has got aspirin’ – then I go back to the hospital and the consultant gives me aspirin to take with warfarin. I found that totally confusing.”

There was some concern about whether a GP might prescribe something that the haematologist was not aware of – or vice versa. One participant had recently had that experience, with his GP unaware of a change of medication from the hospital.

One man queried how much exercise people should take. Rehabilitation is important for heart patients, yet it was unclear whether taking warfarin should affect this. One participant with a stroke said he took exercise once a week, but only did so where there was someone who was trained in life saving:

“If something dramatically happens, you’re covering yourself.”

Holidays were a situation where participants felt that they needed to be careful. Several noted that they had their INR taken both before and after a holiday in case they needed to change the dose:

“They’re very good...they will always fit you in.”

A couple of participants commented on difficulties obtaining travel insurance.

Some issues were raised concerning children, with a particular need for good liaison between the health service and schools; it was important for the latter to understand issues such as bruising, which easily occurred during play or sports. It was suggested that some standard information should be provided to schools about children on anticoagulants.

A few participants had long-standing anxieties about their anticoagulants. One woman was uncertain about the relationship of anticoagulants to both strokes and heart disease and whether the person she cared for was getting the right treatment; the term ‘clot’ seemed to be confusing. A participant was concerned about his frequent admission to hospital for internal bleeding, ascribed to being on warfarin. One woman noted that she had not understood warfarin when she was first put on it, except that it was ‘very important’ and that she would take it forever. A number of participants raised questions about bleeding from cuts or bruising – seen to be somewhat ‘scary’.

12 Sources of information

Given the number of issues about which people need information, a key question is what sources they use. Not surprisingly, many participants tended to ask their doctor and some found them very helpful:

“Two months in hospital and then out and under the GP and at that point we were getting information by booklet. And certainly a very helpful GP, he talked to us about the medication. So that was quite good.”

“I went into a London hospital to start with. When I was discharged, they told me what I had to do, when I had to do it, how I had to do it. There was no problem. Then when I went back again last year, they went through the whole thing again, but it was never a problem of lack of information.”

But some participants raised problems of communication. Some were confident enough to query their doctor, but others found it difficult for one reason or another:

“You don’t want to appear an idiot.”

Some felt that doctors did not try to understand them:

“As you come along in years, it becomes more difficult because the person you’re talking to doesn’t always understand what you’re saying. It could be language, it could be age – they still take the viewpoint that a doctor is like God, you don’t question them at all. If he says that, that’s what it is.”

Several participants with strokes stressed the need for doctors to give appropriate time to patients with aphasia to ensure that they properly understood their medication.

More commonly, however, it was thought to be a question of patients not being sufficiently demanding or not knowing what to ask:

“Part of it is the patients. Instead of saying to the GP, ‘I don’t understand this’, they have said ‘yes’ and walked away dissatisfied.”

“Unless you ask questions, people will not give you the answers. They don’t know that you want to ask a question. You’ve got to open your mouth and ask it.”

Specialist nurses of one kind or another were almost universally praised as a source of information and support:

“Both my epilepsy and my diabetes specialist nurses know more than the clinicians.”

Cardiac liaison nurses, although not always available, were seen as very helpful, especially for parents with children on anticoagulants:

“The big thing is that when things don’t go right, you’ve got somebody you can go back to. People still have direct access to a named person that they know to get 24 hour advice – and usually there’s a very good relationship.”

It was suggested that specialist stroke nurses should be established to serve as the equivalent for stroke patients. In some areas, there were anticoagulant nurses, who ran anticoagulant clinics in the haematology department. These were seen as especially helpful:

“If I thought there was something wrong as a result of warfarin, they would be the ones to ring. They always answer the phone. But again, you don’t really know whether it’s the warfarin or not, do you?”

Local pharmacists were found to be a well regarded source of information, especially about contraindications in taking other drugs. They often kept information on their computers about the drugs already being taken by local people. It was important that it be someone who knew the patient and could be trusted to note that something was inappropriate to take:

“If we buy, say, a pack of Lemsip, he will say, ‘no, you shouldn’t take that, because you’re on warfarin’ – this is what I expect the chemist to do.”

There was some concern that people increasingly bought over-the-counter drugs from supermarkets, where such information would be lacking. A few participants spoke about the knowledge of the hospital pharmacist.

A number of participants belonged to support groups and spoke about their importance as a means of disseminating information. Some invited speakers, such as dieticians, to talk about pertinent issues and they generally made themselves available to members with a query:

“One value of support groups is that people can come back and talk about it in their own way, and test it, and probably share information, such as about the fruit and vegetables.”

It was suggested that such groups should be seen as part of the patient pathway. They could be helpful early on, when people were first diagnosed and had initial worries, as well as later on when there was much less contact with the medical profession.

Some patients used the internet as a source of information – or their sons and daughters did so for them – particularly at the outset of their condition. There was, however, a lot of concern about the accuracy of information found there:

“If [it was] a national health organisation or an organisation that was trusted, it would be a good avenue for people to get information from. If you keyed in warfarin on the computer, what information could we get? It could be very confusing... it might be people’s opinions.”

It was also felt that for something so important, there was a need to talk to someone who knew the specifics of a patient’s situation. In addition, it could be quite worrying:

“If you read too much, you can frighten yourself to death.”

The internet was best seen as a useful way of clarifying information from the doctor:

“As long as you understand the drift, then you can do some research of your own where it will explain it to you.”

Some participants spoke of the value of written material, such as booklets produced by the British Heart Foundation and its monthly newsletter.

The need for more information was a recurrent theme throughout the day. Some felt that they did not need much, except at the early stages of taking anticoagulants. In contrast, some sought out full information at all points, such as one man who said he always read the manufacturer's licence:

"I read that before anything goes into my bod.."

But there was a general sense that more information should be available, not only for patients but also for carers, who felt they were not always well informed. Several participants welcomed the fact that new research findings were sometimes added to their yellow book, in one case via a sticker on the front. A few commented that the provision of information had improved considerably over time:

"When our group started, there was nothing - you were in hospital, you came out of hospital and you were on your own, but now there is much more."

Throughout the discussions, it was a common theme that patients with strokes seemed to have considerably less information and support than patients with heart problems. Not only did they have less attention:

"They're given a bag of tablets and a letter to give to their GP and that's where it stops."

But they also could have difficulty in articulating their problems. The support provided to parents of children with heart problems, in contrast, was thought to be particularly good.

13 Disturbing incidents or concerns

A number of incidents were recounted in the course of the day, where the participant had either been considerably worried or was in genuine danger, such as the man who did not understand that he was supposed to continue to take anticoagulants once the initial supply ran out. These incidents generally centred on experiences in hospital for one condition or another.

A clear source of concern was when doctors themselves did not seem to understand the patient's particular situation. A number of patients suggested this was not uncommon:

"I've had four or five ridiculous readings in the last seven years and I said to the haematologist, 'oops, what's this?' and she always said 'I don't know'."

"Last year, when I had the infarct [*sic*] the doctors came over from one hospital to turn my implant off before they did an MRI scan...the doctors that turned up gave me two months Bacrophen supply in three seconds, which put me into intensive care. They didn't understand the equipment."

One participant said that consultants often did not understand the drugs he was on, even when he offered explanations. As an example, there had been a lack of recognition that Phenindione was an anticoagulant, confusing it with Phenytoin:

"You tell them and their eyes go blank."

He recounted that on one occasion, he allowed a procedure to continue, although he knew it was inappropriate:

“They cut into my groin and the blood came shooting out and I said, ‘well, I did tell you’. Of course, the crash team and everybody else panicked and said, ‘Why did you do that? I said, ‘because I got fed up of telling you that I’m on Phenindione – after five years at the same hospital, you idiots still do not get it through your thick heads’.”

The same man was so dissatisfied with local care that he decided to pay for haematologist care privately:

“I realised early in ‘99 that the haematology department in my local hospital hadn’t got a clue and decided that’s why I was getting nowhere. The one haematologist in the area had got leukaemia and wasn’t seeing patients. They brought in a locum who’d never dealt with haematology problems.”

Another source of anxiety was when doctors provided conflicting advice. One man spoke about a decision by the stroke unit for his partner to go off warfarin, later countermanded by a liver specialist who insisted that she go back on straight away.

Sometimes it was simply a lack of clear explanation that was a source of worry:

“When you’re in hospital, you’re given blood transfusions and you’re transferring all the warfarin out of your blood. When I was in hospital, my warfarin was going along comfortably at three and all of a sudden I had to have two bags of new blood and it shot up to 10. That can disturb you. You don’t know what’s going on.”

“When my partner’s INR shot up before on one occasion, nobody seemed to know why. You’ve got to have an appointment to go through what you’ve been doing, but that wasn’t offered and so you hope that, finger’s crossed, the next reading brings it back to expected, which it did.”

Dentistry was another source of problems. Several participants offered stories of dentists being unaware of the specific needs of people on anticoagulants. One man ended up in Accident and Emergency after going to a dentist who scaled his teeth without giving Amoxicillin, even though she knew he was taking warfarin; she broke his skin and he was still bleeding 24 hours later. The story was also told of a woman whose dentist removed three teeth after giving antibiotics for two days, despite the fact that she had told the dentist that she had had a stroke and a valve replacement and was on warfarin. The woman ended up in hospital with an INR of 6.4.

Another participant had a problem when his dentist was on holiday:

“I had a toothache and I went to see the locum who tried to take the tooth out and broke it. I was then transferred to hospital and they had a hell of a job getting the blood down to the right level. What should have taken just a half an hour ended up taking a month, going backwards and forwards.”

A number of participants were aware of the need to alert a dentist to their situation. It was suggested that their being on anticoagulants should be in their dental records. Dentists should be advised that all dental extractions should be done in hospital. Patients also needed to be much clearer about what they should allow a dentist to do; written information would be particularly helpful here, as it could be shown to the dentist and would carry some authority. Some participants' yellow books were very clear about how to handle dental needs, but not all were.

14 Final plenary

Several participants noted how useful the day had been to them, as it was an opportunity to share information and learn; some had plans to feed back comments to others in their local support group. The hope was also expressed that the NPSA would act on the information:

“We sit in stroke groups moaning about the bad care and whatever, but it doesn't make a lot of change.”

Indeed, the NPSA will be using this report to address the problems as viewed by patients and carers, and to develop solutions to reduce patient safety incidents in this area. Wendy Harris and Peter Mansell thanked everyone for attending and discussing their experiences in such depth.

Appendix 3: References

Reports of patient safety incidents with anticoagulants (13 references)

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